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No. 14

Planning National Radiotherapy Services: A Practical Tool



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PLANNING NATIONAL
RADIOTHERAPY SERVICES:
A PRACTICAL TOOL

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A PRACTICAL TOOL

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

Cancer is a leading cause of death globally. The World Health Organization (WHO) estimates that 7.6 million people died of cancer in 2005 and 84 million people will die of the disease in the next ten years if action is not taken. More than 70% of all cancer deaths occur in low and middle income countries (LMCs), where resources available for prevention, diagnosis and treatment are limited or non-existent. In high income countries, about 50% of new cases of cancer require radiotherapy at least once. Because of the types of cancer, the advanced nature of the cases at diagnosis and the lack of other resources, the proportion of new cases requiring radiotherapy is likely to be much higher in LMCs.

During the last few years, there has been an increased demand from Member States for the IAEA to provide assistance, including the provision of radiation sources and equipment in establishing radiotherapy programmes for the treatment of cancer.

The IAEA is the United Nations system organization with a mandate in nuclear technology transfer for nuclear applications in human health. Through its human health programme, the IAEA coordinates research projects, produces and publishes teaching materials and clinical guidelines, maintains databases, and delivers laboratory services to Member States worldwide.

The Programme of Action for Cancer Therapy (PACT) was established by the IAEA in 2004 in response to the developing world's growing cancer crisis. It builds on previous IAEA experience in radiation medicine and technology — essential in cancer diagnosis and treatment — to assist LMCs cope with cancer by integrating radiotherapy into sustainable comprehensive cancer control programmes.

An earlier IAEA publication, 'Setting Up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects', describes how a radiotherapy centre should be developed, implemented and managed to establish a common and consistent framework in which all steps and procedures in radiotherapy are considered. These include clinical, medical physics, quality assurance and radiation protection aspects.

WHO has published a series of guides that provide advice on how to set up a national cancer control programme. One guide, 'National Cancer Control Programmes: Policies and Managerial Guidelines', has been recently expanded into a series of separate modules that address planning, prevention, early detection, diagnosis and treatment, palliative care and policy and advocacy. The module on diagnosis and treatment of cancer is especially relevant as it outlines the actions needed to bridge any gaps identified in cancer control in low resource countries. It identifies a prioritization strategy that can be used to provide radiotherapy services, taking into account cost effectiveness, appropriateness of

the resource level, affordability and sustainability. This publication aims to fill the gap between planning national cancer control programmes and planning an individual radiotherapy centre. It is aimed at professionals and programme managers involved in the planning or upgrading of national radiotherapy programmes.

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The IAEA officer responsible for this publication was E. Rosenblatt of the Division of Human Health.

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1. INTRODUCTION

1.1. BACKGROUND

Radiotherapy is the safe use of controlled doses of radiation to treat disease, especially cancer. It is usually given by pointing an X ray or gamma ray machine at the part of the body to be treated after the careful planning of where the generated beams will deposit their energy. Radiotherapy can also be given internally by drinking a liquid isotope, delivering it by intravenous injection or by placing a radioactive implant directly into or close to a tumour. Radiotherapy is commonly used together with other treatments such as chemotherapy and surgery. This treatment modality is an essential component in the management of cancer patients, either alone or in combination with surgery or chemotherapy, both for cure or palliation.

Cancer is a leading cause of death around the world. The World Health Organization (WHO) estimates that 7.6 million people died of cancer in 2005 and 84 million people will die of the disease in the next ten years if action is not taken. More than 70% of all cancer deaths occur in low and middle income developing countries, where resources available for prevention, diagnosis and treatment are limited or non-existent. Because of the types of cancer, the advanced nature of the cases at diagnosis and the lack of other resources, the proportion of new cases requiring radiotherapy is likely to be much higher in developing countries.

1.2. OBJECTIVE

During the last few years, there has been an increased demand from Member States for the IAEA to provide assistance, including the provision of radiation sources and equipment in establishing radiotherapy programmes for the treatment of cancer. The objective of the IAEA's human health programme, as well as its Programme of Action for Cancer Therapy (PACT) which was established in 2004, is to assist the developing world in facing the growing cancer crisis. These efforts build on previous IAEA experience in radiation medicine and technology — essential in cancer diagnosis and treatment — to assist developing countries cope with cancer by integrating radiotherapy into sustainable comprehensive cancer control programmes. This publication forms one part of the IAEA's response.

1.3. STRUCTURE

Section 2 provides an introduction to radiotherapy, including the technical aspects of this treatment modality. Section 3 discusses the need for radiotherapy, including the planning of radiotherapy services at the national level using the WHO Stepwise approach. Section 4 describes the tools needed for the strategic development of a national radiotherapy service. Section 5 analyses the costs and economic aspects of a national radiotherapy service. In Section 6, the legal and regulatory framework is discussed. Section 7 describes the steps involved in developing a strategy for a radiotherapy service, while Section 8 describes the steps involved in the implementation of a service, and how it should be monitored. Finally, two annexes provide, respectively, an example of the development of an ambulatory radiotherapy service, and the techniques for precision radiotherapy.

2. TECHNICAL BACKGROUND

2.1. THE NEED FOR RADIOTHERAPY

Radiotherapy is the safe use of controlled doses of radiation to treat disease, especially cancer. It is usually given by pointing an X ray or gamma ray machine at the part of the body to be treated after the careful planning of where the generated beams will deposit their energy. Radiotherapy can also be given internally by drinking a liquid isotope, delivering it by intravenous injection or by placing a radioactive implant directly into or close to a tumour. Radiotherapy is commonly used together with other treatments such as chemotherapy and surgery

This treatment modality is an essential component in the management of cancer patients, either alone or in combination with surgery or chemotherapy, both for cure or palliation. Of those cancer patients who are cured, it is estimated that 49% are cured by surgery, 40% by radiotherapy alone or combined with other modalities and 11% by chemotherapy alone or combined [2].

Radiotherapy is indicated in more than 50% of cancer patients in developed countries [3]. Because of the different types of cancer, the advanced nature of the cases at diagnosis and the lack of other resources, the proportion of new cases requiring radiotherapy is likely to be much higher in low and middle income countries (LMCs) [4].

Its key role in cancer treatment will continue for at least the next 10 to 20 years. Therefore, radiation therapy should be approached as one of the essential components in a continuum of cancer care, and should be incorporated in national cancer control programmes that also include activities in prevention, early detection and palliative care. Such programmes need to be tailored to the particular level of available resources and to the profile of cancer types and stages present in a given country (Fig. 1). Table 1 provides incidence figures for specific cancers across the world's regions.

In high income countries, more than half of all cancer patients treated with radiotherapy — alone or with surgery, chemotherapy or both — are treated with the goal of achieving a cure [5]. Radiotherapy is used alone when it has the highest cure rate or because it is likely to have fewer side effects. Examples include the treatment of cervical cancer, pituitary tumours, deep seated gliomas, nasopharyngeal carcinoma and early stage, low grade lymphomas, including Hodgkin's disease. Some tumours such as advanced cervix cancer can only be cured by radiotherapy.

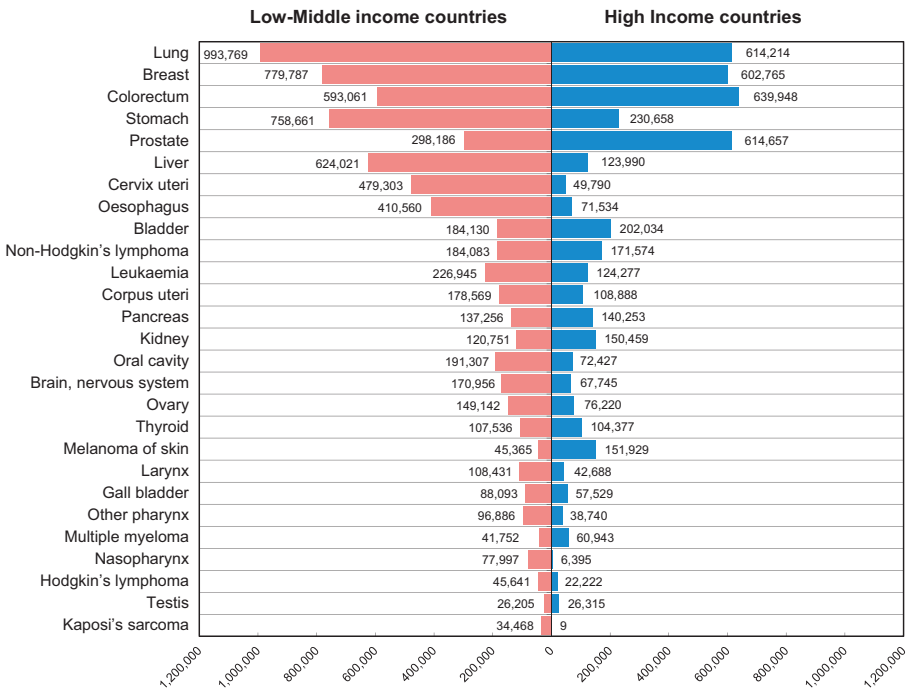


FIG. 1. Worldwide distribution of cancer types in 2008 in high income and low–middle income countries by total number of cases, in thousands. (Incidence data from GLOBOCAN-2008.)

TABLE 1. INCIDENCE OF SELECTED CANCERS (NUMBER OF CASES) BY GEOGRAPHICAL REGION

Region	Lung cancer	Breast cancer	Colon and rectum cancers	Stomach cancer	Liver cancer	Cervix cancer	Oesophagus cancer	Head and neck cancers	Bladder cancer	Non-Hodgkin's lymphomas
North America	225 545	229 535	183 398	24 892	16 206	14 664	15 729	50 921	69 975	61 989
Central America	10 325	14 238	7 549	12 576	4 699	17 162	1 451	5 867	3 267	5 026
Tropical South America	29 609	53 237	31 261	42 643	7 879	40 814	9 128	24 400	11 417	13 580
Temperate South America	14 269	22 616	14 987	9 819	1 761	7 479	3 640	4 710	5 242	3 668
Caribbean	6 283	6 324	5 391	3 541	2 388	6 274	1 371	3 851	1 617	1 536
Western Europe	214 240	246 598	245 804	76 378	35 137	24 531	27 879	86 990	100 978	58 191
Eastern Europe and Northern Asia	172 599	124 159	128 798	109 698	21 370	40 731	20 803	62 734	41 580	17 709
Northern Africa	7 833	13 987	4 979	3 675	2 895	6 491	888	6 277	13 644	3 931
Middle Africa	6 564	43 279	14 775	19 801	46 625	60 647	17 622	26 366	9 147	23 601
Southern Africa	5 065	7 529	3 803	2 579	2 888	11 279	5 719	4 651	2 696	2 366
Middle East	23 568	25 176	16 818	16 656	4 433	4 203	9 418	12 886	10 759	9 998
South Asia	67 148	123 472	41 301	40 889	19 922	152 277	65 593	223 112	22 721	29 728
East Asia	485 426	166 435	261 019	537 234	407 487	60 731	271 049	82 293	49 532	44 925
Southeast Asia	68 443	58 398	44 788	25 618	47 830	42 459	8 026	42 980	9 454	19 203
Southern and Western Pacific	9 961	13 981	15 115	2 647	1 399	1 907	1 558	4 941	3 558	4 315
World	1 346 878	1 148 964	1 019 786	928 646	622 919	491 649	459 874	642 979	355 587	299 766

TABLE 1. INCIDENCE OF SELECTED CANCERS (NUMBER OF CASES) BY GEOGRAPHICAL REGION (cont.)

Region	Prostate and		Pancreatic cancer	Ovarian cancer	Kidney cancer	Endometrial cancer	Brain, nervous system	Melanoma of skin	Thyroid cancer	Hodgkin's lymphoma	All sites excl. skin
	Leukaemia	testicular cancers									
North America	38 494	266 903	34 908	25 152	40 510	51 553	21 119	57 446	22 212	9 695	1 569 851
Central America	6 996	15 073	4 212	4 011	4 289	2 411	3 595	1 570	3 782	1 970	153 628
Tropical South America	15 042	51 628	8 826	10 126	7 216	7 456	12 443	5 781	8 562	2 604	466 810
Temperate South America	3 217	13 007	4 611	2 661	4 393	3 147	1 852	1 751	1 118	726	145 669
Caribbean	1 427	8 923	1 216	836	803	1 598	1 083	386	921	575	64 401
Western Europe	48 075	199 428	45 438	36 765	49 333	43 694	30 374	45 229	15 773	8 900	1 804 206
Eastern Europe and Northern Asia	28 846	45 002	34 745	29 660	38 288	36 536	19 017	18 719	14 499	9 867	1 113 908
Northern Africa	4 402	2 534	1 239	1 306	1 756	1 180	2 459	328	2 100	1 046	99 404
Middle Africa	11 030	22 795	5 004	9 665	5 232	4 696	4 919	5 077	5 214	4 864	458 452
Southern Africa	1 712	5 993	778	1 334	982	895	781	1 908	838	579	88 542
Middle East	11 061	8 598	3 398	3 825	3 787	3 165	7 883	2 236	5 337	4 500	217 009
South Asia	32 481	24 524	10 533	29 698	9 289	10 669	24 561	3 242	18 335	10 757	1 139 490
East Asia	75 036	33 309	67 189	30 422	32 552	20 114	50 276	3 837	27 707	3 124	2 871 446
Southeast Asia	18 622	13 849	7 092	16 848	6 473	9 122	6 827	1 976	12 816	2 417	523 936
Southern and Western Pacific	3 111	14 295	2 206	1 708	2 930	1 960	1 721	10 327	1 325	518	109 958
World	299 552	725 861	231 395	204 017	207 833	198 196	188 910	159 813	140 539	62 142	10 826 710

Source: Globocan [6]

Radiotherapy is preferred over surgery when surgery will result in the loss of an organ or function and the tumour control rate is equivalent. Examples include laryngeal cancer and prostate cancer. Surgery alone can be effective for small localized tumours. For larger tumours, radiotherapy is often used with surgery to reduce the tumour size or reduce the risk of tumour recurrence so that the whole tumour site can be treated with the least effect on the patient's normal functioning. The major advances in combining surgery with radiotherapy to obtain good local control without excess tissue toxicity have come in the management of breast, rectal, head and neck and soft-tissue tumours [2].

Radiotherapy is effective for patients with incurable tumours, alleviating pain, shortness of breath, cough, haemoptysis, and obstruction of organs such as the oesophagus and the urethra. This important role of radiotherapy in the palliative care of cancer patients is particularly relevant in low and middle income countries where, due to the lack of prevention and early detection programmes, the majority of cancer patients present with advanced, often incurable disease.

The proportion of new cases of cancer for which radiotherapy is the treatment of choice is shown in Table 2 by tumour type.

Radiotherapy is one of the most cost effective forms of cancer therapy. The cost per fraction of treatment delivered varies depending on the equipment used and the precision required for its delivery. The real cost of a single fraction of palliative treatment may be less than \$5 in a developing country where staff costs are low [8]. This compares very favourably to some of the chemotherapy regimens, which can only be palliative for metastatic common solid tumours. In high-income countries, radiotherapy is highly cost effective [9]. Palliative radiotherapy is also a cost effective modality [10]. Clearly, the total health economy of a country has to be used to guide the level of radiotherapy provided. However, facilities and treatment machines have a long useful life and can treat a large number of patients over many years of operation. The health gain from the effective use of radiotherapy can be enormous.

Access to radiotherapy services is a multidimensional variable that includes availability of the service, spatial accessibility, accommodation, affordability and awareness of patients and health care providers. The pattern of cancer incidence has a profound influence on the need for radiotherapy in a particular country. The high incidence of a certain tumour type in some populations (such as cancer of the cervix in India and Latin America, oesophagus in the mountains of the Himalayas or nasopharynx in parts of China) will also influence the need for specific radiotherapy resources in a specific region.

TABLE 2. PROPORTION OF TYPES OF CANCER WITH AN INDICATION FOR AT LEAST ONE COURSE OF RADIOTHERAPY

Tumour type	Proportion of all cancers (%)	Proportion with indication for radiotherapy (%)	Optimal proportion of all cancers with indication for radiotherapy (%)
Breast	13	83	10.8
Prostate	12	60	7.2
Melanoma	11	23	2.5
Lung	10	76	7.6
Colon	9	14	1.3
Rectum	5	61	3.1
Gynaecological	5	35	1.8
Head and neck	4	78	3.1
Lymphoma	4	65	2.6
Unknown primary	4	61	2.4
Renal	3	27	0.8
Bladder	3	58	1.7
Leukaemia	3	4	0.1
Stomach	2	68	1.4
Pancreas	2	57	1.1
Central nervous system	2	92	1.8
Other	2	50	1.0
Gall bladder	1	13	0.1
Liver	1	0	0.0
Oesophageal	1	80	0.8
Thyroid	1	10	0.1
Testis	1	49	0.5
Myeloma	1	38	0.4
Total	100		52.3

Source: Delaney [7].

The incidence of cancer is rising dramatically in countries with limited resources due to aging populations, which typically have restricted or no access to radiotherapy. Therefore, implementing and expanding radiotherapy programmes is imperative to ensure the best possible outcomes for all cancer patients. Radiotherapy services are part of a continuum of care that also includes activities in prevention, early detection, diagnosis, treatment and palliative care. Radiotherapy is a mature technology, and detailed modeling shows that it is now indicated in 52% of cancer patients (Table 2). Of those cured of their cancer, which is defined by surviving five years, it is estimated that radiotherapy contributes to that cure in 40% of patients, either alone or in combination with surgery or chemotherapy [2]. It is also effective in a range of palliative situations, the commonest being the control of pain arising from bone metastases [11]. Between 40 and 70% of radiation treatment courses are given with palliative intent.

Radiation therapy is not available to many cancer patients in developing countries for either radical or palliative treatments. The people of some 30 African and Asian countries have no access to radiotherapy (Fig. 2). In many other countries — some with good general healthcare infrastructure — radiotherapy is poorly delivered outside a small number of teaching centres. One recent estimate suggests a global shortage of 5000 megavoltage machines [4].

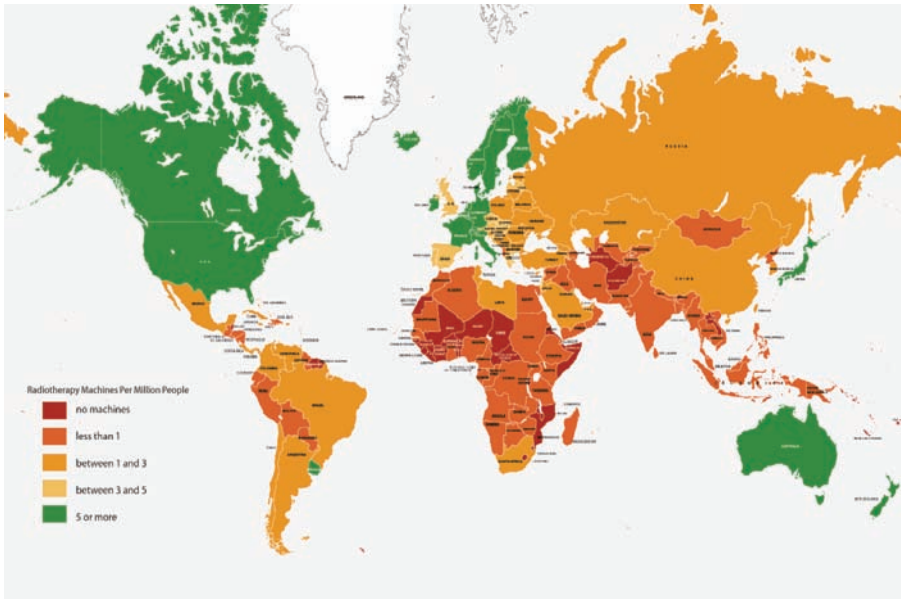


FIG. 2. Availability of radiation therapy — number of radiotherapy machines per million people (Source: DIRAC/IAEA).

Improving the access to and quality of radiotherapy services is an essential component of a comprehensive national cancer control plan.

Although radiotherapy requires a higher initial capital expenditure, it remains a very cost effective component of cancer care. It is usually the lack of an adequate number of qualified staff that limits the offer of radiotherapy services to many patients, especially those living at some distance from the cancer centre [4].

There is now good evidence in several countries, rich and poor, that the utilization rates of radiotherapy are closely correlated to the distance a patient has to travel to obtain treatment. This correlation is stronger for patients of lower socioeconomic and educational background who also will have poorer access to private transport [12].

2.2. OVERALL OBJECTIVES

All countries should aim to establish and develop a radiotherapy service that:

- Meets the cancer burden of the country;
- Is commensurate with the economic resources and national priorities;
- Is set within a national cancer control plan;
- Is sustainable within the economic and human resources of the country.

All countries should ensure the accessibility and effectiveness of diagnosis and radiotherapy services by adopting evidence-based clinical and management guidelines and an essential drug list and by establishing good referral, follow-up and evaluation systems, and continuous training of the different health professionals involved. The sustainability and quality of the operations need to be backed up by a sound equipment management and consumables supply system.

Countries with low to medium levels of resources should organize radiotherapy treatment services to give priority to common, early detectable tumours, or those with high potential for cure such as cancer of the uterine cervix. Countries with a high level of resources should reinforce the development of comprehensive cancer treatment and palliative care centres that are especially active for clinical training and research, and that can act as reference centres within the country as well as at the international level.

Before initiating a radiotherapy programme, the numbers of annual patient treatments need to be estimated. The population within the area from which the institution will draw patients and the annual cancer ratio for that area will yield the approximate number of new cancer patients per year. Approximately 50–60% of these patients will require radiation therapy, alone or as an alternative or adjuvant treatment to surgery. An estimate of how many of these patients will be

seen at the institution should be made and compared to the actual patients seen annually. Unusually high cancer incidence in the area for specific organs/sites (e.g. lung, breast, oral cavity, cervix, oesophagus, etc.) where radiotherapy is more frequently used should be taken into account.

2.3. DEFINITIONS

Radiotherapy, or radiation therapy, is the treatment of cancer and other diseases with ionizing radiation. Ionizing radiation deposits energy that injures or destroys cells in the volume of tissue being treated — the target tissue — and by damaging their genetic material (mainly, the nuclear DNA), thus making it impossible for them to reproduce. Although radiation damages both cancer cells and normal cells, the latter are able to repair the damage more effectively and function properly [13]. One of the greatest challenges of radiotherapy is to minimize damage to normal cells through the delivery of an adequate dose aimed and timed accurately to destroy tumour cells and spare their normal counterparts.

There is a slight but significant difference between the terms ‘radiation therapy’ and ‘radiation oncology’. **Radiation therapy** is a clinical modality dealing with the use of ionizing radiations in the treatment of patients with malignant (and occasionally non-malignant) neoplasms. The aim of radiation therapy is to deliver a precisely measured dose of irradiation to a defined tumour volume with as minimal damage as possible to surrounding healthy tissue, resulting in the eradication of the tumour, an improved quality of life and prolongation of survival.

Radiation oncology is the discipline of human medicine concerned with the generation and dissemination of knowledge concerning the causes, prevention and treatment of cancer and other diseases involving special expertise in the therapeutic applications of ionizing radiation. As a discipline at the juncture of physics, medicine and biology, radiation oncology addresses the therapeutic uses of ionizing radiation alone or in combination with other treatment modalities such as surgery, chemotherapy, oxygen, heat and drugs [2].

Furthermore, radiation oncology is concerned with the investigation of the fundamental principles of cancer biology, the biological interaction of radiation with normal and malignant tissue, and the physical basis of therapeutic radiation. Radiation oncology is primarily concerned with clinical patient care, scientific research and the education of professionals within the discipline.

2.4. BASIS OF RADIOTHERAPY SELECTIVITY

Selective tumour destruction can be achieved in two ways: Precise physical targeting and biological selectivity.

2.5. PRECISE PHYSICAL TARGETING OF X RAY DOSE

Geographically precise deposition of radiation energy to the tumour reduces the dose to normal tissues and permits the safe use of higher doses [14]. Modern tumour localizing techniques involve sophisticated and often costly imaging systems such as computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET), which may not always be available in limited resource settings. By determining the gross tumour volume (GTV), a second volume, the clinical target volume (CTV), can be determined, since it represents the volume of tissue required to be treated to achieve the highest chance of cure. This is incorporated into the planning target volume (PTV) that allows for uncertainties (such as patient's movements and set up errors) in treatment and delivery. The PTV is a geometrical concept designed to ensure that the radiotherapy dose is actually delivered to the CTV. Optimal planning involves the careful assessment of risk to surrounding normal tissues and subsequent modification of the plan to design the optimal balance of benefit versus collateral damage. Optimal planning requires both advanced technology and the close working of experienced staff — radiation oncologists, physicists, dosimetrists and technologists [15].

The rapid developments in medical imaging have spawned a huge range of techniques to deliver far more precision in dose delivery for radical treatments. These include:

- Three dimensional conformal radiotherapy (3-D CRT);
- Intensity modulated radiation therapy (IMRT);
- Image guided radiation therapy (IGRT);
- Respiratory gated radiation therapy;
- Adaptive radiotherapy.

2.6. BIOLOGICAL SELECTIVITY

The second selective mechanism is by the choice of the correct time, dose and scheduling of treatments to optimize the selective destruction of cancer cells while sparing normal tissue. A course of radiotherapy is usually fractionated — given in

daily treatments (fractions) over a number of weeks. The mechanism of selectivity is complex and has been intensely studied over the last 50 years by radiobiologists [13]. A simplistic view is that cancer cells have impaired radiation damage repair mechanisms and thus are less able to repair the damage caused by a fractionated course of treatment when compared to their normal counterparts. Small differences in radiation sensitivity and repair are multiplied by fractionation over several weeks to give greater effect on tumours than normal tissues. Clearly, the way in which radiotherapy courses are fractionated will profoundly affect the overall requirements in terms of equipment, staff and facilities.

2.7. GOALS OF RADIOTHERAPY

2.7.1. Curative

Radiotherapy has a pivotal role in the curative treatment of breast cancer, cervical cancer, cancer of the mouth/pharynx/larynx and others (Fig. 3). Depending on the stage of disease, this modality can reduce the risk of recurrence, improve survival, or provide palliation of symptoms. Radiotherapy can be used to treat cancers that could otherwise not be treated such as nasopharynx or cervix cancer. It can be used to spare organs such as the larynx that would be removed by surgery. Radiotherapy is also used to reduce tumour size prior to surgery or reduce the risk of recurrence when the tumour is close to surgical margins. Radiotherapy is used with chemotherapy for sensitization, because of different side effects, or to achieve higher cell kill in areas of greatest risk such as sites of bulky lymphoma.

2.7.2. Palliative

Palliative radiotherapy is of value in life threatening situations, such as profuse bleeding from a tumour or compression of the superior vena cava. Radiotherapy also provides effective palliation of pain secondary to bone metastases, tumours causing bleeding, or compressive syndromes, such as spinal cord compression or cerebral metastatic disease. A single treatment or a small number of treatments will often have a significant palliative effect at very low cost and obviate the need for more protracted therapy schedules.

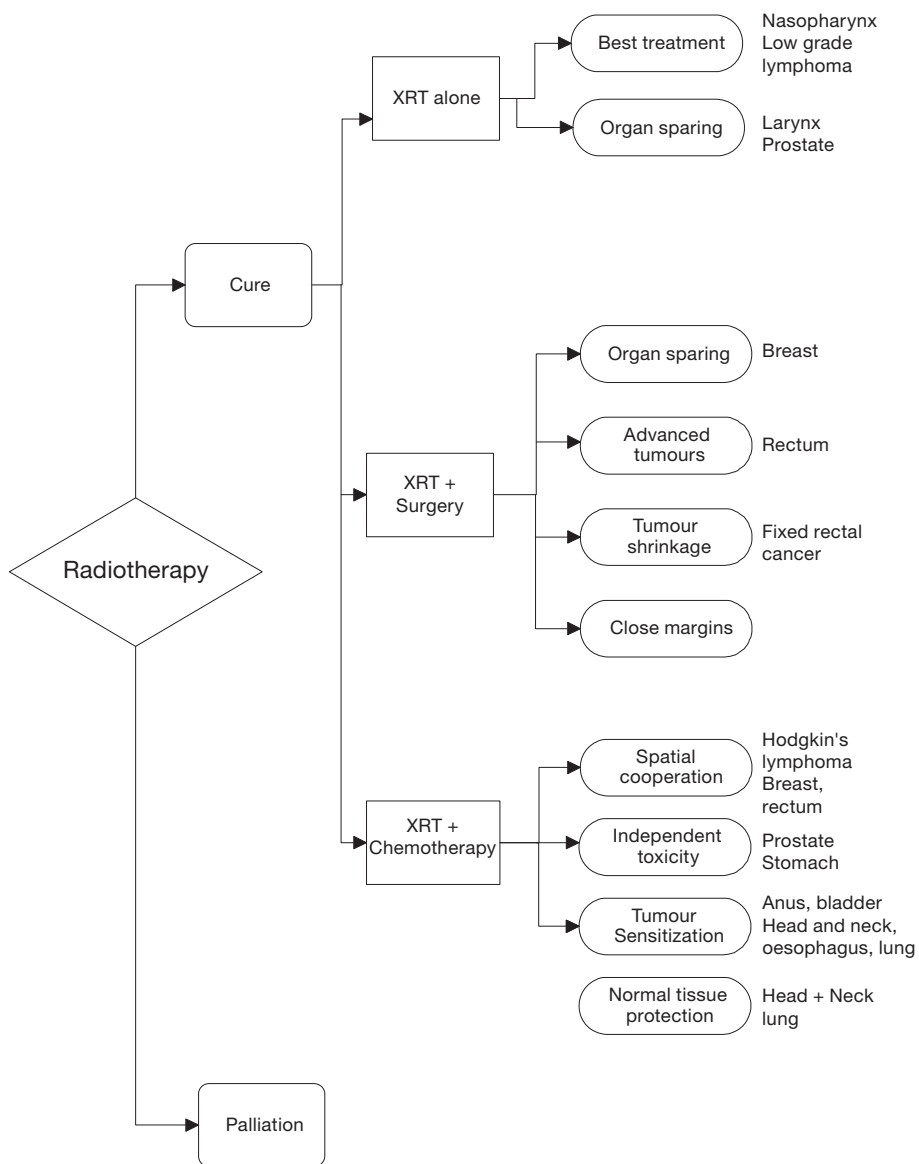


FIG. 3. Scheme of the roles of radiotherapy (XRT) in cancer management with examples of tumour types relevant to different indications.

3. ASSESSING THE NEED

3.1. THE WHO STEPWISE FRAMEWORK

The planning of radiotherapy services at a national level can be approached following the stepwise framework devised by WHO for the development of national cancer control programmes [16]. There is a planning phase followed by an implementation phase, the principles of which are summarized in Table 3.

Obtaining accurate information during the assessment phase is essential. This addresses the question: where are we now? This assessment includes an epidemiological map of the incidence, types and geographical distribution of cancer, the infrastructure and resources currently available to cope with these patients and the current radiotherapy utilization rate (RUR) in a country. The resources that need to be quantified include the number of existing teletherapy machines and radiotherapy fractions given per year per million people, the number of fractions delivered per year by each machine and variation in treatment protocols as measured by the number of fractions given for common indications. This dataset can then be benchmarked with similar information from other countries with a similar health economic landscape.

TABLE 3. THE WHO STEPWISE FRAMEWORK

PLANNING PHASE		
1	Where are we now?	Assess the present state of the cancer problem and cancer control services or programmes.
2	Where do we want to be?	Formulate and adopt policy. This includes defining the target population, setting goals and objectives, and deciding on priority interventions across the cancer continuum.
3	How do we get there?	Identify the steps needed to implement the policy.
IMPLEMENTATION PHASE		
1	Core	Implement interventions in the policy that are feasible now, with available resources.
2	Expanded	Implement interventions in the policy that are feasible in the medium term with a realistically projected increase in or reallocation of resources.
3	Desirable	Implement interventions in the policy that are beyond the reach of current resources, if and when such resources become available.

TABLE 4. DEVELOPING A RADIOTHERAPY STRATEGY APPLYING THE WHO STEPWISE FRAMEWORK

Component	Core With available resources	Expanded With a projected increase	Desirable When more resources are available
Short term 0–5 years	Streamline referral patterns	Increase the number of machines	Create new networks of interlinked radiotherapy centres
	Increase machine efficiency	Increase staff numbers	Develop international links for training and audit
	Increase staff training and capabilities	Increase training of staff	Increase access to precision based radiotherapy
	Install information technology to monitor deficiencies	National audit of radiotherapy by an embedded IT system	Develop distributed network of hub and spoke radiotherapy centres
	Stimulate cooperation and sub-specialization	Invest in specific specialist services	Participate in collaborative clinical trials
Medium term 5–10 years	Increase access to radiotherapy nationally	Invest in health delivery research	
	Overcome geographic access barriers	Create distributed network of interlinked radiotherapy centres	Develop tools for precision RT for all radical treatments
	Reduce need for radical surgery in breast cancer	Ensure that complex planning is available for all radical plans by remote planning services	Develop R&D centres to optimize care
	Increase access for palliative pain control	Dramatically increase the RUR	Stimulate local clinical trials
Long term 10–15 years	Increased reduction in radical surgery	Modernize the equipment stock	International training for all key staff
	Increase the RUR	Develop sophisticated IT and audit	Optimize radiotherapy planning systems
	Increase geographical distribution	Convert cobalt to linear accelerators (linacs)	Develop a long term linac replacement strategy

3.2. ASSESSING THE CANCER BURDEN — CANCER REGISTRIES

Cancer registries are the source of information on the incidence of cancer in defined populations, as well as on outcome in terms of patient survival. They also provide a framework for conducting epidemiological studies into the cause of different cancers. In many parts of the world, cancer registries provide the only available information on the nature and evolution of the local cancer problem. The comparative value of the statistics which cancer registries produce depends upon the use of common methods and definitions, so that international collaboration in this area has a very important role.

It is recommended that all countries have a cancer registry if they wish to develop a rational radiotherapy service. A cancer registry is a systematic collection of data on cancer incidence [17]. Population based cancer registries monitor the incidence of cancer diseases between regions and over time by collecting case reports from different sources: clinicians, pathologists and medical records. If an unexpected accumulation is observed, a hypothesis about possible causes can be generated. This hypothesis is investigated in a second step by collecting more detailed data. The aim is to recognize and to reduce risks. Population based registries can also monitor the effects of preventive interventions.

A national ‘population based’ cancer registry is a vehicle to enable the systematic collection of nationally relevant data on cancer incidence, making it possible to reliably assess the types and prevalence of cancers experienced by populations, assess changes in these patterns over time and therefore assess the impact of any interventions associated with the national cancer control programme in general or interventions related to radiotherapy in particular [18].

For planning radiotherapy, a reliable cancer registry is essential to provide the overall cancer incidence and the relative incidence of individual tumour types. This in turn will allow the identification of those cancer types where radiotherapy is indicated. Ideally, the cancer registry should provide stage information, although this is not always readily obtainable. The profile of cancer types, their stages of presentation and the usual clinical practice in a country will allow the calculation of the potential demand for radiotherapy services.

The optimal partner to drive this component forward is the International Agency for Research on Cancer (IARC) (www.iarc.org). IARC conducts training of professionals and epidemiologists on how to create, conduct and maintain a national cancer registry. In addition, it has collected epidemiology information in a book, *Cancer Incidence in Five Continents*, based on a worldwide database ‘Globocan’, available at the IARC web site. This provides a detailed estimate of cancer patterns and incidence for over 126 countries and is based on the best available estimates where detailed analysis of raw data is not possible [6].

Hospital based cancer registries aim at the improvement of cancer therapy; therefore, they have to collect detailed data on diagnosis and therapy. Improvements can be achieved by:

- Comparing the performance of therapists: which hospital and which physician have the best results;
- Treatment support: registries can improve information and help provide optimal treatment by planning therapies and generating reminders;
- Comparative benchmarking of outcomes with other centres.

Comparisons between therapies cannot be made using registry data because of the difficulty of controlling selection bias. Since the data needed by hospital cancer registries usually include those of population based cancer registries and both use the same classifications, data can be sent from a hospital cancer registry to a population based registry, thus reducing documentation efforts.

The physical location of a cancer registry is often intimately linked to the administrative dependency of the registry. In order to operate effectively, the registry must have sufficient standing to be able to request and obtain detailed demographic and medical information from medical services in the region. It is advisable, therefore, that the registry be linked in some way with government health services (if available) or with professional groups. In some cases, cancer registries are set up and administered by voluntary agencies such as a cancer society. Experience shows that the cancer registry should be as autonomous as possible, since this will best fulfill its needs as an ever-growing organization, and facilitate cooperation with other health agencies and the establishment of direct contacts at both the national and international levels.

3.3. RADIOTHERAPY UTILIZATION RATE

The successful planning of efficient and equitable treatment services for a population requires a rational and robust estimate of demand. This has a particular relevance for planning services that require significant initial capital expenditure such as radiotherapy.

The RUR is defined as the proportion of a specific population of patients with cancer that receives at least one course of radiotherapy during their lifetime.

$$\text{RUR} = \frac{\text{Patients treated with radiotherapy for the first time}}{\text{Total new cases}}$$

Comprehensive information on all the radiotherapy provided for a specific population is required to establish the numerator, and a population-based cancer registry is required to establish the denominator. The optimal RUR is calculated from literature evidence establishing the radiotherapy indications for each disease entity and disease stage according to published evidence-based guidelines.

Establishing an optimal RUR in a specific country provides a benchmark for the planning of radiation oncology services for a population base. A study from Australia provides a good example [7]. For every 1000 cancer cases in that country it has been estimated that 523 (52.3%) would need radiation as an optimal component of their management. The majority are treated with curative intent. A further 120 patients will probably require retreatment (23%). This means that an estimated 643 courses of radiotherapy will be required for every 1000 cancer patients diagnosed with cancer. This method allows a population based estimate of the possible number of treatment courses and therefore the amount of resources (facilities, equipment, staffing) that should be provided for any particular country. Epidemiologic data from the patterns-of-care type of study allows comparison to be made between the actual rates of radiotherapy delivery and the evidence based ideal rate.

Table 5 shows the RURs in 15 common forms of cancer in four high income countries and compares them to the optimal utilization rates calculated from literature evidence [7]. The information provided here reflects the practices in industrialized countries where radiotherapy facilities are widely available. The variations in RUR in the four industrialized countries are probably related to differences in relative accepted indications for radiotherapy and surgery in these countries.

However, these figures may not be applicable to all countries because of variations the distribution of types of cancer, stage of disease at presentation, indications for treatment, and likely future availability of equipment and trained personnel. For instance, in low income countries, and due to the relative paucity of effective prevention, screening and surgical services, a higher proportion of patients may present with advanced stage disease making radical surgery impossible. It is possible that in such countries an optimal RUR may be as high as 60–80%. In this scenario, the majority of patients treated in radiotherapy departments are treated with a palliative intent.

The RUR can be used to obtain a practical estimate of the demand for radiotherapy under ideal conditions. The optimal number of radiotherapy fractions per cancer patient and per treatment course, may be added to the optimal RUR model. An evaluation of the optimal number of fractions per course needed for patients with common cancers such as lung, breast, oesophagus and prostate can be made. This parameter together with an estimate of the number of patients with each particular type of cancer allows a calculation of the total number of

TABLE 5. RATE OF PATIENTS RECEIVING RADIOTHERAPY FOR THE 15 MAJOR CANCERS IN FOUR COUNTRIES AND THE PERCENTAGE OF OPTIMAL RUR

Cancer site	Sweden (1)	Netherlands (2)	Australia (3)	USA (4)	% optimal RUR (5)
Oral cavity and pharynx	94–100	54	44	70	74–100
Oesophagus	73	—	47	54	80
Stomach	7	—	6	15	68
Rectum	56	28	17	41	61
Liver	0	—	3	—	0
Larynx	100	78	80	75	100
Lung	71	46	38	39	71
Breast	81	63	41	44	83
Cervix	83	60	41	33–44	58
Endometrial	64	47	26	25	46
Ovary	—	9	—		—
Prostate	51	31	44	41	60
Bladder	17	37	26	4	58
Lymphoma	40	47	24	—	65
Leukaemia	8	—	6	—	4
All sites except the skin	43	33	25	24	52

fractions required to be delivered. These data provide a valuable benchmark for service delivery and for comparison with the actual fractionation used in practice. Such an analysis can also be applied to predict future radiotherapy workload and hence aid in future radiotherapy services planning. This model can be adopted and modified for different populations and for future changes in cancer incidence, stage distribution, treatment recommendations and evolving radiotherapy fractionation recommendations subject to their economic viability.

A good example of such an analysis to calculate the optimal number of fractions per treatment course for 23 cancer types in Australia has recently been developed. Table 6 presents their extracted data for 13 cancer types.

TABLE 6. OPTIMAL NUMBER OF FRACTIONS PER PATIENT AND PER TREATMENT COURSE FOR 13 CANCER TYPES

Cancer site	Proportion of all cancers (%)	Optimal radiotherapy utilization (%)	Optimal No. of fractions per new case of cancer	Optimal No. of fractions per treatment course
Central nervous system	2	92	27.4	29.8
Head and neck	4	78	23.0	29.5
Oesophagus	1	80	17.1	21.4
Stomach	2	68	17.0	25.0
Rectum	5	59	15.6	26.4
Pancreas	2	57	13.2	23.2
Lung	10	76	13.1	17.2
Lymphoma	4	65	9.6	14.8
Gall bladder	1	13	3.2	24.6
Colon	9	14	3.0	21.4
Myeloma	1	38	0.4	1.1
Leukaemia	3	4	0.3	7.5
Liver	1	0	0	0

Source: (K. Wong, personal communication, 2008).

3.4. ASSESSMENT OF EXISTING FACILITIES

An initial evaluation is necessary to describe all resources (personnel, equipment and space renovation) required to address the identified clinical needs such that the resultant programme conforms to acceptable standards of practice.

This evaluation should include:

- An overview of the existing national hospital infrastructure to support diagnosis and staging as well as other oncology facilities;
- A description of the existing radiotherapy programmes, including staff, the facilities available and utilization versus capacity;
- Specific geographical features of a country or a region that make access a particular issue; these need to be identified at the outset.

- Description of additional major pieces of equipment, personnel and major space renovation or construction. The division of costs, between the institution and its sponsors should be addressed.
- Description of and justification for additional personnel needed. Emphasis should be placed on having adequate professional radiation oncology staff (physicians, physicists, dosimetrists, radiation therapy technologists (RTTs) radiation oncology nurses and maintenance engineers) to support the radiotherapy programme without jeopardizing other programmes.
- Description of any institutional deficiencies in specific areas, such as quality assurance, radiation protection and maintenance.
- Description of existing equipment procurement plans (teletherapy machines, simulators, sources, remote afterloaders, planning systems).
- Description of external training plans for the radiation oncology professional staff, as well as the need for on-site technical experts for training and helping to manage programme implementation and monitoring its progress.
- Continuing professional education programmes.
- All major construction and space renovation plans.

3.5. DIRECTORY OF RADIOTHERAPY CENTRES (DIRAC)

The mandate of the IAEA is to ensure that nuclear energy is used for peaceful purposes and to ensure that it is used in the safest possible way. The objective of the IAEA human health programme is to enhance the capabilities of Member States to address needs related to the prevention, diagnosis and treatment of health problems through the application of nuclear techniques. The mandate arises from Article II of the IAEA Statute:

“The IAEA shall accelerate and enlarge the contribution of atomic energy to peace health and prosperity throughout the world”.

Since 1959, the IAEA has maintained a computerized database of radiotherapy centres worldwide called DIRAC (Directory of Radiotherapy Centres). In 1995, data collection and storage in a database were systematized and distributed on CD-ROM, and later made available on the web in 2004 [19]. The database incorporates information from various sources such as national databases and information provided by professional societies, manufacturers and radiotherapy centres. The current version allows direct on-line updating of information by radiotherapy centres, which in turn is checked by the IAEA.

At present, data have been collected from 160 countries. The database contains information on 7001 radiotherapy centres, with 12 324 teletherapy machines, of which 9821 are medical linacs and 2503 are cobalt-60 (⁶⁰Co) units. There are 2661 brachytherapy systems (low dose rate (LDR) and high dose rate (HDR)). The database contains information on the number of staff and the number of patients treated every year.

Recently, DIRAC has undergone substantial revisions and is being updated in order to make data available to users worldwide through the IAEA's web site at <http://www-naweb.iaea.org/nahu/dirac>. A password to enter detailed site areas is necessary. DIRAC includes the following data for each individual centre:

- Radiotherapy equipment (cobalt units, linacs, X ray units);
- Brachytherapy equipment (types of sources, machines for remote afterloading);
- Dosimetry equipment (chambers, electrometers, beam analysers, monitoring instruments);
- Treatment planning systems;
- Simulation equipment (simulators, CT simulators);
- Staff strength (number of radiation oncologists, medical physicists, technologists and nurses);
- Number of patients treated per year (with teletherapy and with brachytherapy).

The database is stored on an SQL server, and data are extracted through queries.

4. TOOLS TO ASSIST WITH STRATEGIC DEVELOPMENT

4.1. THE WHO NATIONAL CANCER CONTROL PROGRAMME

Cancer control aims at reducing the incidence, morbidity and mortality from cancer and to improve the quality of life of cancer patients in a defined population through the systematic implementation of evidence based interventions for prevention, early detection, diagnosis, treatment and palliative care. Comprehensive cancer control addresses the whole population, while seeking to respond to the needs of the various subgroups at risk.

As defined by WHO, a national cancer control programme (NCCP) [18, 19] is a public health programme designed to reduce the number of cancer cases and deaths and improve quality of life of cancer patients, through the systematic and equitable implementation of evidence based strategies for prevention, early detection, diagnosis, treatment, and palliation, making the best use of available resources. A comprehensive national cancer programme evaluates the various ways to control disease and implements those that are the most cost effective and beneficial for the largest part of the population. It promotes the development of treatment guidelines, places emphasis on preventing cancers or detecting cases early so that they can be cured, and provides as much comfort as possible to patients with advanced disease.

It is essential to set priorities since the resources will likely not be enough to meet all health needs. Priority setting is particularly important in resource constrained settings, because of the need to make the best use of often very limited resources. Therefore, it is important that the committee guiding the overall cancer control planning process establish the criteria for selecting priorities.

To ensure that diagnosis and treatment services are effective and efficient, they should be part of a national cancer control plan and should initially prioritize patients with curable types of cancer. Later, when more resources become available, these services should be extended to patients with cancers that are treatable but not curable, thus ensuring full coverage of all patients suffering from cancer. In following the model of WHO national cancer control programmes, four main areas of activities should be included.

4.1.1. Prevention

Cancer preventive measures, especially when integrated with chronic disease prevention (such as reproductive health, HIV/AIDS, occupational and environmental health), offer the greatest public health potential and the most cost effective, long term method of cancer control. There is enough evidence available to prevent approximately 40% of all cancers. Many adult cancers are linked to tobacco use, unhealthy diets and infectious agents. Tobacco control, human papilloma virus vaccination, healthy lifestyles including dietary measures and physical activity are examples of activities included in the prevention component.

4.1.2. Early detection

Early detection including screening detects disease at an early stage, when it has a high potential for cure. Interventions are available that permit the early

detection and effective treatment of around one third of cases. There are two strategies for early detection:

- *Diagnosis*. This often involves the patient’s awareness of early signs and symptoms, leading to a consultation with a health provider, who then promptly refers the patient for confirmation of diagnosis and treatment.
- *Screening*. This strategy involves the screening of asymptomatic, apparently healthy individuals to detect pre-cancerous lesions or an early stage of cancer, and to arrange referral for diagnosis and treatment. Screening programmes using cytology, visual inspection, mammography or occult blood in stools are examples.

4.1.3. Treatment

Treatment aims at curing the disease, prolonging life, and improving the quality of remaining life after the diagnosis of cancer if confirmed by the appropriate available procedures. Treatment is most effective and efficient when linked to early detection programmes and follows evidence based standards of care. Cancer treatment is based on three mayor pillars: surgery, radiotherapy and chemotherapy. There is continuous research in other areas such as gene therapy and immunological therapies. This component should also include rehabilitation aimed at improving the quality of life of patients with impairments due to cancer or its treatment. It is important to underscore the close link between early detection (including screening) and cancer treatment. An excellent screening programme would be inappropriate (even ethically questionable) without effective treatment measures. Similarly, it is useful to encourage early detection. Early detection reduces the burden on patients and the treatment system because treatment is simpler and more likely to be successful.

4.1.4. Palliative care

This component should meet the needs of all patient requiring symptomatic relief and psychosocial and supportive care, particularly those which advanced stages who have a very low chance of being cured or who are facing the terminal phase of the disease. Cancer and its treatment have emotional, spiritual, social and economic consequences for patients and their families; palliative care services addressing their needs from the time of diagnosis can influence their quality of life and their ability to cope effectively. Availability of opioids for pain control, in particular oral morphine and hospice services, are examples of activities related to this component.

4.2. CANCER CENTRES

The term ‘cancer centre’ has no universally accepted definition. In high income countries, cancer centres are the focal points for cancer treatment advances and research. Cancer centres are actual, physical places, although they may differ in how they are organized. Usually, cancer centres are single institutions (one building or one campus) that specialize first and foremost, in the diagnosis and treatment of cancer. In other cases, the cancer centre may be a cancer unit within a larger hospital, such as a university affiliated medical hospital that treats the full range of health conditions. In still other cases, the cancer centre is actually a consortium of hospitals or institutions that operate in an integrated cancer programme. As in high income countries, cancer centres in LMCs also act as focal points for cancer control nationally and as points of contact internationally. Both these functions are important. Being a recognizable international point of contact can bring substantial benefits to the centre. Cancer centres pioneer new treatments, establish the state of the art in treatment and other aspects of cancer control, and act as a reference centre for the country. Either formally or informally, leader institutions in regions where cancer control is poorly developed may also act a reference training centres or perform other leadership roles.

The pattern of financing cancer centres in LMCs may be different from that in high income countries. Ideally, the government will support at least some functions, and the cancer centre will be officially recognized or designated as a *national cancer centre*.

In LMCs where a large proportion of the population does not have health insurance, and cancer care is expensive relative to their income, most people may find it impossible to pay for cancer services on their own. Without covering the costs of treatment, and possibly additional expenses incurred by patients and their families (e.g. commuting, subsistence and accommodation for their family), a cancer centre may be essentially inaccessible, even for those living nearby. A mixture of public and private (including philanthropic) funding may be needed to allow access to a wide range of patients.

Countries should consider establishing at least one government-supported cancer centre that provides appropriate services to the public and acts as a reference point for national cancer control. This could be a new centre or an existing one may be designed as such. International organizations and other partners should assist in developing and improving cancer centres in LMCs through twinning arrangements, resource mobilization and other means. The core functions that cancer centres in LMCs should strive to offer include the following:

- *Patient care*. This includes surgery, radiotherapy, chemotherapy, imaging, pathology, supportive psychosocial services and palliative care. Patient care includes collection of follow-up data to allow the evaluation of the clinical outcomes of treatment in terms of disease control and toxicities.
- *Training*. This is needed in all functions and services that should be provided at the cancer centre, as appropriate to the needs and resources of the country. In all countries, there should be training available for RTTs and radiation oncology nurses. In most centres, there should also be programmes for radiation oncologists, medical physicists, surgeons and others.
- *Continuing professional development*. This focuses on upgrading and updating skills and knowledge of established health professionals. This is especially important for non-medical staff because they have reduced access to conferences and overseas travel.
- *Research*. The focus here is on clinical questions of particular local importance.
- *Cancer prevention*. This refers to early detection programmes, locally and nationally, that are tailored to resource levels.
- *Community outreach*. This includes education of the public and of health providers, preventive programmes, and community based palliative care with pain management using oral morphine.
- *Communications and information technology*. This refers to the need to adopt at an early stage low cost, advanced technology for a number of purposes, including linking the country internally and externally.
- *International partnerships*. The international health community has until now established relatively few activities related to cancer in LMCs. The reasons for this are complex but include the perceived relative burden of cancer in comparison with other public health problems.

4.3. THE IAEA'S PROGRAMME OF ACTION FOR CANCER THERAPY (PACT)

PACT was set up by the IAEA in 2004 in response to the developing world's growing cancer crisis. Drawing on the IAEA's 30 years of experience in radiation medicine and technology, PACT aims to assist developing countries build a comprehensive, sustainable cancer control programme integrating prevention, screening, treatment and palliative care.

PACT works with WHO and other leading cancer organizations to develop joint programmes and raise funds for cancer treatment and care where they are most needed. The IAEA believes such public–private partnerships are essential to address future cancer needs in the developing world. In the short term, PACT seeks to raise cancer awareness, assess needs and develop demonstration projects to attract donors. PACT has formulated the following three point strategy to implement its aims:

- (1) To identify and assess a country's most pressing cancer needs so that partners and donors can effectively respond.
- (2) To establish pact demonstration sites as an example of the value and efficacy of multidisciplinary, interagency cooperation in combating cancer. Such sites will highlight PACT's activities and help raise public awareness as a forerunner to larger regional and global initiatives. Model demonstration sites selected to date include Albania, Nicaragua, Sri Lanka, the United Republic of Tanzania, Vietnam, Ghana, Yemen and Mongolia.
- (3) To set up comprehensive regional training networks for health care professionals. In particular, it aims to encourage trained staff to stay in their home countries with ongoing professional development programmes and investment in modern technology and facilities including web based learning.

PACT promotes the concept of national cancer control planning as the most efficient way to tackle the cancer problem in a country. Each country has particular features in terms of its cancer burden, cancer risk factors, culture, health system, and available financial and human resources as well as infrastructure. These features should be carefully assessed in order to establish realistic and achievable priorities for action.

To assist ministries of health in this regard, PACT offers a comprehensive needs assessment review service called 'imPACT'. Any IAEA Member State can request an imPACT review of their cancer services by contacting the PACT Programme Office.

4.4. PLANNING A SERVICE

Radiotherapy is a complex process (Table 7) and requires capital and staff investment. The needs and abilities of individual countries will differ significantly. A 'one-size-fits-all' plan would be doomed to failure by setting standards too low or too high and by raising unrealistic expectations. Each LMI country should prepare, with the aid of WHO/IAEA and other agencies, a cancer

TABLE 7. THE PROCESS OF RADIATION THERAPY (TELE THERAPY)

1. Clinical evaluation	Multidisciplinary evaluation of the patient Decision for radiation therapy Assessment of the tumour Staging
2. Therapeutic decision making	Selection of treatment goals — cure/palliation Prescription Determination of dose–time–volume relationship
3. Patient immobilization	Achieving treatment region immobilization
4. Target volume determination	Definition of tumour extent and potential routes of spread Identification of sensitive organs and tissues Measurement of patient; construction of patient contours
5a. Planning simulation	Selecting position of simple field arrangements
5b. Treatment planning	Selection of treatment technique Selection of modality and energy Selection of field directions for complex field arrangements Shaping of fields Computation of dose distribution and verification of accuracy Dose volume histogram
6. Fabrication of treatment aids	Construction of custom blocks, compensating filters
7. Simulation of treatment	Radiographic documentation of treatment ports and shielding blocks
8. Treatment	Transfer of treatment data to the treatment machine Initial verification of treatment setup Verification of accuracy of repeated treatments Continual assessment of equipment performance Periodic checks of dosimetry, record keeping
9. Patient evaluation during treatment	Evaluation of tumour response Assessment of tolerance to treatment
10. Follow-up evaluation	Evaluation of tumour control; assessment of complications

control plan that specifically examines the need for radiotherapy based on local resources, types of cancer and other relevant conditions. An example of the development of an ambulatory radiotherapy service is given in Annex I.

Regarding curative therapy for cancer in general, the priority actions in the framework of a national cancer control programme should be to:

- Ensure the accessibility to effective diagnostic and treatment services.
- Promote national minimal standards for disease staging and treatment.
- Establish management guidelines for treatment services, essential drugs and continuous training.
- Ensure curative therapy is available when appropriate and to offer palliation when cure is not achievable.

Key to describing the operation of a radiation oncology facility is the need to consider its four principal components: equipment, consumable materials, human resources and procedures. The basic components necessary to establish a fully operational radiotherapy clinic in a resource limited setting are presented in Table 8. Provision must also be made to assure availability of staff salaries, consumables and for equipment maintenance and repair.

The aim of a comprehensive integrated cancer service should be to integrate the delivery of care into patients' lives in order to allow them to carry on with their previous level of activity including work, leisure and social activities. The product needs to be a standardized service across all centres and this standardization is created through common protocols and efficient processes. Centres will be positioned in easily accessible locations. Each centre will have one or two teletherapy machines and chemotherapy. Radiotherapy planning may or may not be undertaken at the site.

4.5. RADIOTHERAPY GUIDELINES AND CALCULATING DEMAND

There have been several approaches to estimating the demand for radiotherapy. Comparisons are commonly made on the basis of ratios of linear accelerators or staff per million population [20]. However, cancer incidence also varies markedly between countries and it is therefore better to make a comparison between the crude number of new cases per year because this gives a real estimate of the potential caseload. An evidence based calculation method can be applied to estimate the overall optimal RUR for a given population or country, according to the common types of cancers encountered (Table 2). An example from Europe is given in Annex II.

TABLE 8. A STEPWISE APPROACH TO ESTABLISHING AND DEVELOPING RADIOTHERAPY CENTRES

1st level — Core: The basic radiotherapy centre

(The following lists the equipment that should be found in every cancer therapy centre that aims to treat a significant number of patients with cervical cancer with curative intent)

- 1 teletherapy unit (in new centres with possible unstable power and poor environmental controls, the IAEA would recommend cobalt machines rather than linacs)
- 1 HDR brachytherapy machine (when a large number of patients with cancer of the cervix are treated annually)
- 1 mould room capable of producing immobilization devices and custom radiation shields specifically for individual patients treated curatively
- 1 simulator (either conventional or CT simulator) as an aid to planning treatments
- 1 treatment planning system (TPS) with a level of sophistication matched to the complexity of the treatments performed
- 1 set of dosimetry equipment capable of performing reference and relative dosimetric measurements and QA tests to verify proper operation of the therapy equipment and the treatment planning process.
- 4–5 Radiation oncologists
- 3–4 Medical physicists
- 7 Radiation therapy technologists
- 3 Radiotherapy nurses
- 1 Maintenance engineer

2nd level

- Has at least the above equipment and staff
 - Provides a sustainable and adequate radiotherapy service
 - Acts as a model and reference centre at the country level
 - Has a QA programme
 - Has a patient follow-up programme
 - As part of the QA programme, conducts a systematic analysis of own treatment outcomes
 - Has training programmes for some or all of the radiotherapy related professions at the national level
-

TABLE 8. A STEPWISE APPROACH TO ESTABLISHING AND DEVELOPING RADIOTHERAPY CENTRES (cont.)

3rd level

- Operates self-sustainably through education
 - Has training programmes for some/all the radiotherapy related professions at the regional level
 - Acts as a model and reference centre at the regional level
 - Conducts a hospital based or national based cancer registry
 - Engages in cancer control activities: prevention and screening
 - Engages actively in research contributing to the published literature
-

The proportion of patients that should benefit from radiotherapy is roughly considered to be about half of the general cancer incidence; in addition, about a fifth to a fourth of these patients could receive re-treatment afterwards. In the coming years, an increase of about 20–30% in numbers requiring treatment is expected, mainly due to the aging of the population.

Megavoltage X ray units can treat between 400 and 600 courses per year. The potential number of new cases with an indication for radiotherapy and the number receiving second or subsequent courses can then be used to calculate the number of megavoltage units required in a geographical region.

4.6. OPTIMAL GEOGRAPHICAL LOCATION OF RADIOTHERAPY SERVICES

Where should cancer radiotherapy centres be located? The intuitive answer is that radiotherapy centres should follow the population concentration distribution in a country. A single centre may suffice in small countries or even in large countries with a small population if transport services between centres of population are adequate. In general, however, a network of oncology services will be required, with a radiotherapy centre within each region of a country. For those patients living at a distance from the radiotherapy centre, funding will have to be set aside to pay for the costs of transport and accommodation facilities.

Countries where a significant proportion of the population are living at a distance or geographically isolated from the main centres may also consider either the implementation of consultation clinics as focal points for further

referral (primary care clinics can fulfill this role), or alternatively, facilitate patient commuting through organized transport services.

A study from Ontario, Canada [21], showed that the Province's highly centralized radiotherapy network did not provide adequate or equitable access to care to the province's dispersed population. In this study, the RUR was 29% at eight years, which is much lower than the generally accepted rate for a developed country. A similar study from the northern part of England showed socioeconomic gradients in access to services [22] related to education levels and car use.

4.7. EQUIPMENT

The essential equipment and staffing for a basic radiotherapy clinic are presented in Table 8.

4.7.1. Teletherapy

Teletherapy is also called external beam radiation therapy (EBRT). The origin of the radiation beam is from within a radiation shielded head, which has a small opening through which the radiation beam can pass and diverge. The radiation beam is aimed at the region of the body with cancer as well as at the sites at risk for disease spread, with effort made to reduce the dose received by healthy tissues and organs. The treatment is usually administered on a daily basis over a 5–7 week period. The treatment takes place in an enclosed shielded room (a bunker) and no anaesthesia is needed for adult patients. Teletherapy may be administered by cobalt machines, by medical linacs or by orthovoltage machines.

Cobalt machines are more robust and less expensive both to buy and to maintain. Basically, the machine consists of a source of radioactive ^{60}Co (half-life 5.3 years), which emits gamma rays as it decays shielded within a lead container with an electrically controlled shutter. When this opens, a beam of gamma rays is emitted. The dose rate is predictable and minimal checks are required. The maintenance of cobalt machines is relatively simple. Due to radioactive decay, the source has to be changed at regular intervals of five to six years to keep the treatment time from becoming excessive. Access to enriched ^{60}Co is becoming increasingly difficult and more expensive. Source security has also become a concern.

Linacs are more expensive and require more demanding maintenance and frequent calibration. Electrons produced by an electrical current are accelerated down a tube one meter or longer like surfers on waves. They hit a tungsten target at the end of the tube where their energy is changed into X rays and heat. The

higher dose rates provided by accelerators reduces treatment times and will also permit a more accurate delineation of treatment fields. However, to take full advantage of these features, advanced imaging, planning and immobilization are required. In the absence of a service contract, breakdowns of major components may represent a significant unplanned emergency expense. The annual cost of maintenance is approximately 10% of the purchase cost.

Experience in countries with limited resources has shown that the downtime of linacs is generally considerably greater than for cobalt machines. This is now changing with modular design allowing for regional stockpiling of key modules for replacement within 24 hours (in developed countries). Linacs are much more versatile in delivering precision volumes and faster to operate. An additional advantage is the availability of electron beams, which are used in about 15% of radiotherapy patients in situations where the irradiation of superficial tissues is required without irradiating deeper structures.

In general terms, newer and advanced technology should not be accepted at face value. Careful assessment of current outcomes, operating costs, maintenance and staffing requirements is essential. In the past, for the majority of cancers in developing countries, linear accelerators offered little advantage over cobalt machines. With the advent of modular design based on the aviation model, the defective part can be replaced and sent for repair. Contracts for linacs guaranteeing less than 2% downtime are now common in developed countries provided there is good geographical access. However, many linac companies require payment before providing expensive spare parts. This may result in long interruptions to service. Interruptions to radiotherapy can lead to treatment failure, tumour recurrence and death. For example, interruption in the treatment of cervix cancer increases the risk of death by 1% per day [23]. Linacs require stable water and power supplies; otherwise, their operation and safety may be compromised.

The treatment rooms shielding should be designed in accordance with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) Report 151 [24], paying due regard to the requirements of the Basic Safety Standards (BSS) [25] and the national regulatory authority.

4.7.2. Brachytherapy

In certain clinical situations brachytherapy is usually administered in addition to teletherapy. In the case of cervical cancer — a frequent disease in many developing countries — its use is mandatory if the intent is to cure the disease. In brachytherapy treatments, the radiation source is in close contact with the tumour. *Brachy* is derived from the Greek meaning *short*. The radiation source is usually placed inside an applicator in the uterus and vaginal vault in the

case of cervical cancer. This is called intracavitary brachytherapy. With this technique the tumour in the cervix and its extensions receive a very high dose, but the healthy organs such as the urinary bladder and rectum receive a much lower dose. Effectively, the insertion of a linear source within the uterus and two small sources into the upper end of the vagina delivers a pear shaped high dose volume to irradiate a primary cervical cancer and its likely routes of spread.

Brachytherapy may be delivered by a number of different techniques: low dose rate (LDR) by the manual insertion of caesium (^{137}Cs) sources, LDR with automatic and remotely controlled insertion or high dose rate (HDR) using iridium (^{192}Ir) or cobalt (^{60}Co) sources. HDR can be used in the treatment of cervical cancer as well as several other cancers. HDR reduces the need for hospital bed occupancy and eliminates exposure of the staff as opposed to LDR, but demands more expertise and has higher capital costs.

Cost calculations show that when the number of cervical cancer patients is high, HDR brachytherapy is more cost effective than LDR. An admission of 2–3 days associated with LDR brachytherapy in developing countries may result in higher cost per patient than outpatient treatments with HDR, even if the initial capital cost is higher for HDR.

Disadvantages of HDR brachytherapy using Iridium sources are related to the costs of operation and maintenance, especially in LMCs due the number of sources changes needed three–four per year). New systems using a miniaturized cobalt-60 source may contribute to solve this problem.

4.7.3. Other equipment

In addition to the teletherapy and brachytherapy equipment, quality treatment by radiotherapy requires additional quality assurance tools such as an imaging device (a conventional or computed tomography simulator), immobilization devices, shielding devices, a treatment planning computer system and physical dosimetry tools. The delivery of safe and effective radiotherapy also requires addressing certain logistical issues. Specifically, in addition to the staff and equipment requirements, the health care system must be able to provide the physical facility for radiotherapy, the supply infrastructure (water, electricity, waste management) support systems that allow delivery of therapy over a period of weeks, initiation of treatment without long delays, and geographic accessibility to patients.

The type, amount and level of sophistication of the equipment do not determine the level of a centre's performance. Rather, this is determined by its ability to operate self-sustainably through education and to engage in the analysis of its own treatment outcomes, thereby providing guidance for others and creating impact in the country or region (Table 8). It is only when a centre is able

to provide evidence demonstrating that it has achieved the status at least of a centre of competence and preferably of excellence that managers should seek to introduce sophisticated or leading edge technology that requires a much higher level of education and training for implementation to be effective and sustainable.

The justification for specialized equipment within a radiation oncology service is fundamentally related to the following:

- Contextual definition of conventional versus specialized equipment;
- Availability and impact of standard or conventional equipment;
- National burden of cancer that is to be serviced;
- Availability and sustainability of human resources and infrastructure to support a highly specialized service.

4.7.4. Defining conventional versus specialized radiation oncology equipment

In high income nations, conventional equipment is often equated with specialized equipment as technological transfer and implementation is dynamic and has ongoing momentum. Institutions offering clinical radiation oncology services are often involved in the research and development of the above mentioned innovative technology. As a result, long term, systematic clinical trials proving that better outcomes and survival are indeed achieved as a result of technology alone are almost non-existent [26]. Radiobiological principles of dose escalation, reduction in normal tissue complication probabilities, smaller treatment margins, computer control and automated quality control procedures are simply and intuitively assumed to be superior.

In LMCs, technology transfer is far more complex as a result of service demands. Philosophically, the emphasis on modernity is superseded by the need for sustainability and reliability. Maximizing cure rates in LMCs for early stage disease may then not be necessarily realistic in approach. Maximizing the number of cured patients while managing high numbers of patients who could be presenting with advanced disease, lends itself to a cost–benefit approach. The definition of quality care is then relative to the national ability to support appropriate technology [18]. Competence and excellence in radiotherapy delivery implies sustainability within an achievable sound quality management system.

4.7.5. Availability and impact of conventional radiotherapy equipment

Centres with limited infrastructure and resources, seeking to optimize the impact of radiotherapy within a health system, can achieve a large degree of sustainability with the following set of equipment:

- Conventional radiotherapy simulation of simple isocentric techniques;
- Basic computerized treatment planning techniques;
- Simple and practical immobilization aids and accessories;
- Teletherapy with a cobalt unit or linear accelerator;
- A computerized, networked patient database system capable of verification;
- A brachytherapy service.

Assuming an eight hour working day, a megavoltage teletherapy service offering in terms of daily visits of patients on a radical course of treatment could be provided to a minimum of:

- 32 breast patients, i.e. 260 new patients per annum receiving 31 fractions each. This assumes a treatment time of approximately 15 minutes each;
- 60 gynaecological patients (this would imply an equivalent HDR brachytherapy service of approximately 10 patients per day), i.e. 420 new patients per annum receiving 30 fractions each. This assumes a treatment time of approximately 5–10 minutes each;
- 50 head and neck patients, i.e. 350 new patients per annum receiving 35 fractions each, assuming a treatment time of 10 minutes; or
- A pro rata combination of the above.

Similarly, additional megavoltage teletherapy and brachytherapy units or an extension of the working day would increase the impact on the disease burden accordingly. The latter would also need to be supported within the staffing framework. It is therefore clear that models in which the number of new cases of cancer is directly linked to the requirements for equipment are perhaps too simplistic. Progressing to three dimensional treatment planning and conformal radiotherapy techniques would, however, not have as much of a major initial cost impact, but would require an increase in expertise, manpower and quality management.

Ironically, the equivalent service level impact cannot be met with highly specialized equipment within the same budget envelope, despite claims of technological automation. Introducing a multileaf collimator, for instance, would double initial and ongoing costs, and require additional expertise, staffing and quality management. Introducing computer controlled intensity modulation and adaptive radiotherapy dramatically reduces the number of daily visits possible and similarly, increases the patient specific demands on manpower. Ancillary costs are also increased to ensure better target volume definition using other imaging modalities, for instance, or more sophisticated immobilization techniques.

4.7.6. The national burden of cancer being serviced

The reality of translating between the national cancer incidence and the requirements for radiotherapy equipment is often influenced by:

- National policies or infrastructure which promote or obstruct accessibility to the service;
- Lack of epidemiological data;
- Optimistic expectations of human resource capabilities;
- Patient education and demand for treatment.

4.7.7. Techniques of precision radiotherapy

It is clear, however, that if the number of early stage curative patients requiring radiotherapy is well known, then the need for specialized equipment should be based on the availability of human and economic resources. The advent of modern computers has revolutionized the versatility of its delivery. A decade ago, conformal radiotherapy became standard practice by delivering an optimized conformation to the target volume in three dimensions. Pinpoint accuracy is now possible by using two new techniques — IMRT and IGRT[27]. Together, these allow the construction of easily reproducible plans to deliver a homogenous dose conforming to any possible shape, however irregular, while continuously monitoring the position of the actual cancer within the delivered beams. More details of precision techniques are given in Annex II.

4.8. STAFFING

The staffing needs of radiotherapy services should also be carefully reviewed (Table 9). To make radiotherapy available to all patients who need it, human resources should be urgently expanded globally together with the careful acquisition of additional equipment. The recommended staffing for a facility with two teletherapy machines is reviewed in Tables 8 and 9. Where possible, training should be undertaken in centres with patient populations, equipment and training programmes relevant to the needs of the country. Radiotherapy staff should also be required to obtain a qualification adequate for registration in their own country. The set of equipment and the list of human resources listed above could treat on average about 1000 patients per year by extending operations to a minimum of 12 hours per day.

TABLE 9. PERSONNEL REQUIREMENTS FOR CLINICAL RADIATION THERAPY

Category	Staffing
Radiation oncologist-in-chief	One per programme.
Staff radiation oncologist	One additional for each 200–250 patients treated annually. No more than 25–30 patients under treatment by a single physician. Higher numbers of predominantly palliative patients could be managed.
Radiation physicist	One per centre for up to 400 patients annually. Additional in ratio of 1 per 400 patients treated annually.
Treatment planning staff	
Dosimetrist or physics assistant	One per 300 patients treated annually.
Mould room technician	One per 600 patients treated annually.
Radiation therapy technologists (RTTs)	
Supervisor	One per centre.
RTT	Two per megavoltage unit up to 25 patients treated daily per unit, 4 per megavoltage unit up to 50 patients.
RTT-Sim	Two for every 500 patients simulated annually.
RTT-Br	As needed.
Nurse	One per centre for up to 300 patients treated annually and an additional one per 300 patients treated annually.
Social worker	As needed to provide service.
Dietician	As needed to provide service.
Physical therapist	As needed to provide service.
Maintenance engineer/electronics technician	One per two megavoltage units or one megavoltage unit and a simulator if equipment is serviced in-house.

The equipment and staffing indicated would be sufficient to start operations but would certainly not be sustainable without adding a training component. Hence, to qualify as a *centre of competence*, the clinic should at least provide training to replace its own technologists and continuous education programmes to ensure the best possible quality of services in the long term. In addition, it should ideally be able to provide financial resources to enable academic training for replacement radiation oncologists and medical physicists as well as on-site clinical training for these professionals.

4.9. PROCEDURES

The radiotherapy process (Fig. 4) is complex and particular attention must be taken to ensure that it is safely implemented. A centre of competence should practice and promote a culture of QA as evidenced by written policies and procedures guiding the treatment of its patients, and regular preventive maintenance of its equipment. Peer review of the clinical procedures, regular evaluation of morbidity and mortality (with special attention to unanticipated adverse events) and regular analysis of short term and long term outcomes with regard to tumour control for the most common types of cancer is essential by regularly following up the treated patients.

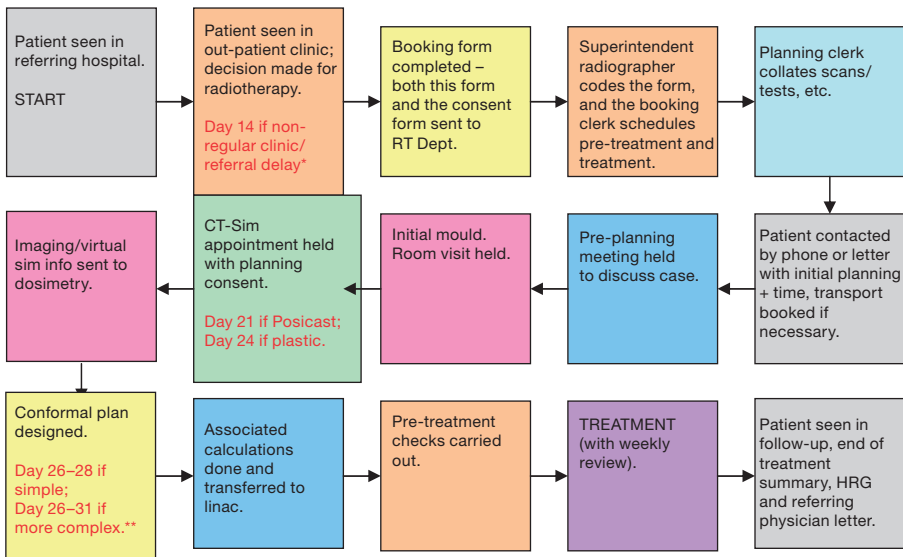


FIG. 4. Pathway for a typical radiotherapy patient.

4.10. MULTIDISCIPLINARY APPROACH

The optimal care of cancer patients is a multidisciplinary effort that may combine three or more disciplines: surgery, radiation oncology and medical oncology. Multidisciplinary treatment protocols that include components of surgery, radiation and medical oncology are common practice. Non-oncological medical or surgical staff will usually make the first clinical diagnosis of a cancer. Multidisciplinary care improves the outcomes of cancer care, increases utilization of treatment and promotes efficiency.

A well established patient referral policy should be in place to avoid or minimize delays in the initiation of treatment. One of the most important goals of a national cancer control programme is to ensure effective procedures to refer the patient between primary and secondary care levels. Undergraduate medical training should include a core curriculum to teach cancer skills and knowledge to a generalist level so that future practitioners are better informed about cancer prevention, detection, treatment and palliation.

Each hospital (or group of hospitals) should have a number of specialized combined assessment clinics (tumour boards or multidisciplinary teams), staffed by practitioners experienced in the management of regional cancers. Tumour site oriented multidisciplinary committees are valuable and should evaluate the patient before the treatment process, defining the clinical stage and in accordance guiding the subsequent steps of treatment and follow-up. The clinic members are responsible for preparation of an institutional clinical management protocol in accordance with the resources and skills available.

4.11. QUALITY ASSURANCE AND RADIATION SAFETY

Quality assurance in radiation oncology is a set of processes and procedures designed to confirm that radiation therapy will be or was administered appropriately and safely and documented properly. QA measures, such as the IAEA Intercentre Dosimetry Project, helps ensure that accurate doses are delivered. Programmes are also required to develop common evidence-based protocols to standardize patient treatment. Treatment protocols specific to local regions would give guidance on best practice and reduce wasteful variation.

The establishment of a radiation safety committee in a hospital is a useful adjunct in controlling the use of radiation within a hospital and as a route of communication with the hospital administration and the regulatory authorities. The Committee should have representatives of all users of radiation within the hospital; diagnostic radiology, nuclear medicine, radiotherapy and, in some cases, biochemical and pathology laboratories.

The committee must include the equipment licensee (or his nominee), the radiation safety officer, clinicians, medical physicists, radiographers and maintenance engineers. The purposes of the committee are to continuously invigilate the standards of personnel monitoring, equipment and practice to ensure compliance with the International Basic Safety Standards (BSS). An active hospital radiation safety committee is considered to be a powerful tool in the prevention of radiation accidents in the hospital as well as ensuring adherence to optimal medical practice.

Further guidance is given in the WHO Radiotherapy Risk Profile: Technical Manual [16]. A suitable regulatory environment must be in place with a national radiation safety act that delineates roles and reporting responsibilities (see Section 5).

5. COST AND ECONOMIC ANALYSIS

5.1. CAPITAL AND RUNNING COSTS

The cost of establishing a new radiotherapy facility in an LMC is about \$5–6 million. If operated for 12 hours per day, it could deliver half a million doses of radiotherapy over its lifetime, with an amortized cost of less than \$5 per fraction [8].

Managers should be aware that starting or expanding a radiation therapy programme involves much more than acquiring new equipment. It is essential to allocate adequate funds for staff, treatment planning and dosimetry equipment, training, patient follow-up and outcome analysis. Provision must also be made for ongoing needs, such as preventive maintenance and repairs, source replacement and an adequate stock of spare parts. The half-life (the time it takes for the radioactivity to decay to half of its original activity) of a cobalt source is 5.3 years. This means that the time taken to treat a patient, will double every 5.3 years. By 10.6 years (two half-lives) treatment will take four times as long.

Plan resource allocation for:

- Building facilities;
- Equipment;
- Treatment equipment;t
- Treatment planning equipment;

- Clinical and physical QA equipment;
- Preventive maintenance and repairs;
- Radioactive source replacements (when applicable);
- Consumables;
- Staff training for continuing development and replacement;
- Staff salaries;
- Patient follow-up and outcome analysis.

Although the initial investment in establishing radiotherapy is significant, the long life of the major radiotherapy equipment (20 years) means that the cost per patient treated can be surprisingly modest in an efficiently run facility. The average operational life of a cobalt machine may be around 20 years, sometimes even longer. Linear accelerators, simulators, CT scanners, treatment planning systems and conventional radiology units, have an effective lifetime of up to ten years, provided there is a working maintenance system in place.

An efficient radiotherapy service can be remarkably cost effective. The costs per patient treated are low if the equipment is used optimally, as most of the costs are initial capital expenditure with relatively low running costs or consumables. Thus, savings from reduction in personnel, that reduce machine use, can increase the costs per patient treated to a level far beyond the savings realized. Nonetheless, given that substantial initial investment and in light of the competing needs in countries with limited resources, collaborative and innovative approaches are called for. For example, technical cooperation programmes between nations or with international organizations such as the IAEA can aid the establishment of radiotherapy in countries with limited resources.

Advances in telecommunications may also enable cost effective approaches by linking radiotherapy facilities with differing levels of treatment capability and expertise by digital networks or satellite. Continued exploration of such strategies will be essential to meet the goal of delivering radiotherapy to cancer patients. Transparency and accountability mechanisms of health care expenditure are essential and should be put in place early in the process. The increase in the number of teletherapy machines in developing countries is closely linked with the gross national income per capita (GNI/cap) of a country.

5.2. COST PER RADIOTHERAPY FRACTION

In 2002, the IAEA conducted a survey [8] with the participation of 11 developing countries to determine the cost of a daily radiotherapy treatment (fraction) delivered with a ^{60}Co unit or with a linac. The costs per fraction were

predominantly determined by three components: the number of fractions given per year, the capital costs of the machine and the costs of QA and maintenance.

An analysis of the combined cost components per fraction delivered showed a range from \$1.29 to \$34.23 for cobalt machines, with a median of \$4.87, and from \$3.27 to \$39.59 for linacs, with a median of \$11.02 [8]. As far as the investigated components were concerned, a treatment fraction on a linac with functionality comparable to cobalt costs 50% more than on a cobalt machine.

It was striking in this study that the costs of ^{60}Co sources vary by a factor of >10 . Low costs are found in countries that produce their own sources locally, but high costs in other countries were difficult to explain. There was no clear explanation as to why some countries had to pay up to three times more than the real price of a ^{60}Co source, other than extra costs due to local regulations, insurance rates and transportation costs. Factors affecting specifically the costs of cobalt machines are the national regulations regarding handling and disposal of radioactive sources.

Age and technical specifications such as functionality are primary factors influencing the initial capital cost of linacs. There is also an inter-country variability, which depends on secondary factors such as insurance and import duties, agents fees, the total equipment package purchased (e.g. whether this includes treatment planning systems, CT scanners, simulators and validation systems). Other factors sometimes play a role such as extended warranty or maintenance contracts including some or all spare parts, as well as whether or not training is offered to the personnel.

5.3. ECONOMIC ANALYSES

Payers are and will be increasingly interested in knowing whether they are receiving value for the resources they spend on health care. Because economic analyses will be used as a means of evaluating radiotherapy, it is important to understand the basic methodology employed in such analyses.

Although other factors may have a strong influence on how health care resources are allocated, economic analyses does provide a starting point from which to begin when comparing competing treatment strategies.

An economic health care analysis attempts to relate explicitly the additional cost of an intervention to its benefit. Interventions are always evaluated relative to an alternative form of treatment. Economic analyses are therefore incremental analyses. The issue is not how much an intervention costs per unit benefit, but how much more it costs per unit benefit compared to a reasonable alternative. The incremental approach is used because if the proposed treatment is not given, by

default some other strategy will be employed; even no treatment can have costs and benefits.

5.3.1. Cost minimization

If the benefits of competing treatments are assumed to be identical, the preferred treatment from an economic standpoint is the one that results in the lowest cost. The results are simply reported in currency units (e.g. dollars). Generally, cost minimization analyses are the easiest type of economic analyses to perform. By assuming that the benefits of competing treatments are identical, the analysis is simplified considerably. Only costs, not benefits, must be calculated and compared.

5.3.2. Cost effectiveness

Cost effectiveness analyses relate the additional costs of an intervention to its incremental impact on a clinically relevant measure of benefit. For example, the cost of treatment per breast cancer detected by screening mammography or the cost per episode of neutropenia averted by the use of growth factors. Benefit is often measured in units that are universally applicable (and thus comparable) to all interventions. Years of life saved are the most commonly used measure. However, when interventions have a significant impact on quality of life, an economic analysis that looks only at years of life saved may be misleading.

5.3.3. Cost utility

Cost utility analyses are a subset of cost effectiveness analyses that correlate the additional cost due to treatment to its impact on both survival and quality of life (QOL). A QOL weighting factor is used and called the 'utility factor'. The result is a measure of QOL adjusted survival known as 'quality adjusted life years (QALY)'. Results are reported in units of dollars per QALY.

5.3.4. Cost–benefit

Cost–benefit analyses relate the additional cost of treatment to its incremental benefit as compared to the most reasonable alternative treatment. The additional amount spent due to the treatment is then subtracted from the additional amount accrued as a result of treatment. An intervention is thus considered 'cost beneficial' if the difference is >0 . Cost–benefit analyses are appealing because their results are reported in units that are universally understood and measured. However, to perform a cost–benefit analyses, one must

be able to measure accurately in dollars the value of such variables as an additional year of life, local tumour control or an improvement in quality of life. Questions remain as to their validity and whether their use is ethical. Thus, to date, only a small number of true cost benefit analyses of medical treatments have been performed.

5.4. ACCESS, ETHICS AND EQUITY

A more difficult question is how much access and equity will be demanded in the delivery of radiotherapy. This obviously has a cost. The broad field of medical ethics also applies to the practice of radiation oncology. In addition, there are many potential sources of ethical tension in the practice of radiation oncology, both in every day practice and in the realm of clinical research. Areas of concern include, but are not limited to, those presented in the following list:

- Financial arrangements with hospitals and referring physicians including fee-for-service arrangements that create perverse incentives;
- Professional time dedicated to ‘private’ institutions at the expense of the ‘public’ ones;
- Breach of patient’s confidentiality; disclosure of information;
- Fraudulent claims to the government or reimbursing institution;
- Indiscriminate application of newer technologies to generate higher revenues;
- Incentives from manufacturers/industry sponsors;
- Financial factors in the medical decision process (such as ‘managed care’ systems);
- Medical errors and malpractice litigation;
- Decision making in problem individual cases:
 - Patient non-compliance;
 - Genetic counselling;
 - Paediatric oncology decisions;
 - Patient/family conflicts;
- Patient’s rights;
- Code of ethics in radiation oncology research.

In cases such as these, individuals with formal training and experience in clinical medical ethics can provide the expertise needed to sort through the ethical, legal and social issues involved. In this setting, the establishment of a permanent hospital ethics committee can be very valuable.

Inequalities in health reflecting inequalities present in society as a whole abound; cancer incidence and patterns are a proof of it. A close look at cancer rates according to socioeconomic, racial and ethnic groups reveals some significant differences. Differences in cancer incidence, prevalence and mortality, burden of cancer and related adverse health conditions have been described as health disparities.

There is sufficient evidence that people with lower socioeconomic status experience greater cancer incidence and shorter survival times after a cancer diagnosis. Yet, socioeconomic status, a function of income, education and occupation, does not itself cause cancer or poor outcomes. Rather, it is a marker for underlying physical and social factors that cause disease, recurrence and reduced survival. Socioeconomic effects may be explained by differences in health care access between socioeconomic status groups. These differences may be due to problems with transportation, time off work and child care, all of which may be more difficult to solve for people of low socioeconomic status. Such difficulties can lead to access problems along the entire spectrum of care, starting with early detection issues and delays in diagnosis after the appearance of initial symptoms. Together with logistical barriers to access, people of lower socioeconomic status are more likely to be uninformed about early detection programmes and disease management, including the early signs, symptoms and availability of cancer treatment.

Health care disparities arise from a complex interplay of economic, social, and cultural factors. Socioeconomic factors exert influence on some cancer risk factors such as tobacco use, poor nutrition, physical inactivity and obesity. On the other hand, income, education, and health insurance coverage affect the access to appropriate early detection, treatment, and palliative care services. Cultural factors also play a role in health behaviour, attitudes toward illness, and trust in modern medicine versus alternative forms of healing. It would be unrealistic to attempt to find a molecular explanation for the difference in incidence and mortality for most cancers between more and less affluent socioeconomic groups. However, it is likely that many more genetic and epigenetic alterations that have been identified so far are required to complete the process of carcinogenesis. This would eventually explain in molecular terms the epidemiologically demonstrated effect of environmental exposures.

While the social and economic burden of cancer will continue to accumulate in developing countries, there are promising efforts under way in the scientific, medical, economic and policy arenas that will likely have a positive impact on the availability and effectiveness of interventions available for care and the quality of life for individuals with cancer.

The cost of cancer care is another key point when addressing cancer disparities. This varies dramatically according to the disease and its stage, and

whether curative therapy is still to be attempted. There are doubtlessly enormous limitations in the use of cancer resources in developing countries. Apart from the cost of the treatment itself, cancer management generally requires the participation of a number of trained professionals, who are in short supply in developing countries.

More recently, studies describe that a number of patients from lower socioeconomic groups not only are diagnosed with and die from preventable cancers, but also are diagnosed with late-stage disease for cancers that are detectable at an early stage through screening. These patients receive either no treatment or treatment that does not meet currently accepted standards of care, die of types of cancer that are generally curable, suffer from terminal cancers in the absence of adequate pain control and other forms of palliative care.

6. LEGAL AND REGULATORY FRAMEWORK

6.1. REGULATORY AGENCIES

The purpose of the BSS [25] is to place requirements on those “legal persons” authorized to conduct practices that cause radiation exposure or to intervene in order to reduce existing exposures. These legal persons have the primary responsibility for applying national standards. Governments, however, have responsibility for their enforcement, generally through a system that includes a regulatory authority, and for planning and taking actions in unusual circumstances. In addition, governments generally provide for certain essential services for radiation protection and safety, and for interventions that exceed or complement the capabilities of the legal persons authorized to conduct practices.

Before initiating construction of a radiotherapy facility, approval has to be obtained by the national regulatory authority. The BSS can only be implemented through an effective radiation safety infrastructure that includes adequate laws and regulations, an efficient regulatory system, supporting experts and services, and a ‘safety culture’ shared by all those with responsibilities for protection, including both management and workers. Guidance on the practical implementation of the standards of safety in medical exposure as established by the BSS can be found in Ref. [26], while more specific guidance for regulators and users of radiation sources in radiotherapy can be found in Ref. [27].

6.2. NATIONAL INFRASTRUCTURE

Essential parts of a national infrastructure are: legislation and regulations; a regulatory authority empowered to inspect and authorize regulated activities and to enforce the legislation and regulations; sufficient resources; and adequate number of trained personnel. The infrastructure must also provide ways and means of addressing societal concerns that extend beyond the legal responsibilities of the legal persons authorized to conduct practices involving sources of radiation. For example, national authorities ensure that appropriate arrangements are made for detecting any buildup of radioactive substances in the general environment, for disposing of radioactive waste and for preparing for interventions, particularly during emergencies that could result in exposure of the general public. They also need to provide for the control of sources of radiation for which no other organization has responsibility, such as natural sources and radioactive residues from past practices.

The national infrastructure must provide for adequate arrangements to be made by those responsible for the education and training of specialists in radiation protection and safety, as well as for the exchange of information among specialists. A related responsibility is to set up appropriate means of informing the public, its representatives and the media about the health and safety aspects of activities involving exposure to radiation and about regulatory processes. This provides information to facilitate the political process of setting national priorities and allocating resources for protection and safety and also helps to make the regulatory process more readily understandable.

The national infrastructure must also provide facilities and services that are essential for radiation protection and safety, but are beyond the capabilities required of the legal persons who are authorized to conduct practices. Such facilities and services include those needed for intervention, personal dosimetry and environmental monitoring, and for calibration and inter-comparison of radiation measuring equipment. Services could include the provision of central registries for occupational exposure records and the provision of information on equipment reliability. The provision of such services at the national level does not detract from the ultimate responsibility for radiation protection and safety borne by the legal persons authorized to conduct the practices.

6.3. REGULATORY AUTHORITY

Full and proper implementation of the BSS requires that a regulatory authority be established by the government to regulate the introduction and conduct of any practice involving sources of radiation. Such a regulatory

authority must be provided with sufficient powers and resources for effective regulation and should be independent of any government departments and agencies that are responsible for the promotion and development of the practices being regulated.

The regulatory authority must also be independent of registrants, licensees and the designers and constructors of the radiation sources used in practices. The effective separation of responsibilities between the functions of the regulatory authority and those of any other party is to be made clear so that the regulators retain their independence of decision and judgment as safety authorities.

A single regulatory authority may be responsible for all aspects of radiation protection and safety in a country. In some countries, however, regulatory responsibility for different practices or different aspects of radiation protection and safety may be divided between different authorities. Consequently, the term ‘Regulatory Authority’ is generally used in the BSS to mean the relevant regulatory authority for the particular source or aspect of radiation safety in question. Regardless of the division of regulatory responsibilities, the government must ensure that all aspects are covered: for example, it must ensure that a specific body is assigned responsibility for the regulatory surveillance of protection and safety measures for patients and of quality assurance measures for equipment and techniques for medical uses of radiation.

The type of regulatory system adopted in a country will depend on the size, complexity and safety implications of the regulated practices and sources, as well as on the regulatory traditions in the country. The mechanism for carrying out regulatory duties may vary, with some authorities being completely self-sufficient and others delegating some inspections, assessment or other duties to various government, public or private agencies. A regulatory authority may also be self-sufficient in specialist expertise or may consult expert advisers and advisory committees.

The general functions of the regulatory authority include the following:

- The assessment of applications for permission to conduct practices that entail or could entail exposure to radiation;
- The authorization of such practices and of the sources associated with them, subject to certain specified conditions;
- The conduct of periodic inspections to verify compliance with the conditions;
- The enforcement of any necessary actions to ensure compliance with the regulations and standards.

For these purposes, mechanisms are needed for notification, registration and licensing of the sources within practices, with provision for the exclusion or exemption of sources or practices from regulatory requirements under certain conditions. Provision is also needed for the surveillance, monitoring, review, verification and inspection of sources and for ensuring that adequate plans exist for dealing with radiation accidents and carrying out emergency interventions. The effectiveness of radiation protection and safety measures for each authorized practice and the total potential impact of authorized practices need to be assessed.

The powers of the inspectors of the regulatory authority must be well defined and consistency of enforcement must be maintained, with provision for appeal by those responsible for sources. Directives to both inspectors and regulated legal persons must be clear. The regulatory authority may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example, in regulatory guideline documents. An attitude of openness and cooperation must be fostered between regulated legal persons and inspectors, which include facilitating access by inspectors to premises and to information.

An additional responsibility of the regulatory authority is to require all parties involved to develop a safety culture that includes: individual and collective commitment to safety on the part of workers; management and regulators; accountability of all individuals for protection and safety, including individuals at senior management level; and measures to encourage a questioning and learning attitude and to discourage complacency with respect to safety. Due account needs to be taken by both the Regulatory Authority and the regulated legal persons of general experience and of new developments in radiation protection and the safety of sources.

7. DEVELOPING A STRATEGY

7.1. COLLECTING THE DATA

The data described in the previous sections need to be carefully collected, verified and analysed, allowing for, an outline plan to be constructed. This has to be realistic from an economic viewpoint at the outset. The draft plan will need to be circulated widely to ensure broad agreement to its principles. The best method is through the non-communicable disease division of a country's health department, which will almost certainly hold responsibility for radiotherapy

development. A specific group needs to be charged with the creation, consultation and implementation of the plan. An advisory group of health professionals with a multidisciplinary background are necessary as a reality check and to provide expert guidance throughout the development and implementation of the strategy.

7.2. CONSULTING WITH HEALTH PROFESSIONALS AND SERVICE USERS

At a draft stage, extensive consultation with health professionals and service users is required. This is essential to avoid a top-down approach that will hinder its implementation. A working document that is broadly acceptable can then be fine-tuned to take into account local views in specific geographical areas. A series of working groups can then be held with health care professionals and patient representatives to obtain local input. Conflict of interest between different groups is inevitable and will require diplomatic resolution by senior Department of Health staff. This is most likely to arise from the closure of ineffective radiotherapy departments or their move to more logical and convenient locations. The advent of distributed models of care should help to resolve some of these issues.

The plan will need to incorporate future changes in clinical care services and training in several associated specialties including imaging, histopathology, surgery and medical oncology, all of which are vital to good patient care. Planned local developments will need to be realistically evaluated by staff on the ground.

7.3. CONSULTING WITH DECISION MAKERS AND THE PRIVATE SECTOR

Cancer is a politically important disease in all countries. Politicians from all parties need to be consulted about proposed changes and their views sought. Local versus national interests have to be finely balanced to develop a win-win approach rather than creating confrontation through competition and discord. The importance of the role of radiotherapy in the management of malignant disease must be stressed at a time of considerable excitement surrounding the use of new and expensive molecularly targeted therapy, which for most patients can only be palliative.

Increasingly global health reform has involved private sector investment. The development of an effective radiotherapy strategy will require considerable funding. Whether to involve the private sector, who will naturally seek a return on its investment, will ultimately be a political decision.

7.4. FINANCING THE STRATEGY

The business plan for the preferred strategy will need to be transparent. Capital investment and its revenue consequences will need to be considered separately. Indeed, there is no point in creating a structure that cannot be afforded or sustained financially. There are essentially five sources of funding:

- Government: from taxation.
- Health insurance organizations: may be social, mutual or for profit.
- Private sector investors who will be looking for a revenue stream: preferably guaranteed by government or an insurer on a take or pay basis. Such guarantees are often difficult to achieve for the lifetime of a linac.
- Private–public finance partnerships: Here the private sector builds and in some cases commissions and runs the centre and in turn is paid a yearly fee for a set period, usually well in excess of ten years.
- The equipment manufacturer who may either provide leasing finance directly or arrange this with a partner: ‘Pay per click’ arrangements are common in the software industry.
- Charitable organizations: who may make donations to specific projects.

In most developments, a mixture of funding streams is likely. In all cases, the realistic linking of the revenue consequences of any capital outlay must be clearly defined. If the business plan is risky, then the cost of money will be greater irrespective of the system used.

7.5. DEVELOPING PARTNERSHIPS

Creating partnerships from the outset is essential to reduce risk. There are many examples of successful partnerships between the public and private sector in healthcare. Redistributive billing practices whereby richer private patients are charged more than poor patients, hence improving the quality of care achieved by both are common in many areas of medicine. Richer patients may simply travel abroad for their care. This often results in a downward spiral of local services as revenue is lost.

7.6. PROJECT MANAGEMENT PLANNING

A detailed project plan with time line and cost is vital. This must include all the ramifications of the strategy — local, regional and national.

At a local level, emphasis should be placed on appropriate water and electricity supplies and adequate lighting. A plan for clinical implementation including procedure and QA programme development, training of ancillary personnel, and programme initiation should be developed in enough detail so that a budget can be prepared. A plan for equipment acquisition and commissioning should be developed consistent with the training of staff and the pace at which new technology can be integrated into patient care. Finally, a master budget should be prepared. The entity — such as hospital administration or national government — responsible for funding each major item should be clearly identified. The institution's commitment to the project, including funding, is essential. This budget should include the costs of running and maintaining the equipment over a 10–15 year life expectancy including service contracts, source replacement and source repatriation arrangements. Further, in order to ensure the long term sustainability of radiotherapy services, depreciation and replacement planning need to be included in the financial plan.

This involves comparing the programme needed with the existing resources, and identifying additional needs. The options selected will depend on many factors: patient load, clinical training, biases and the institute's interest, and availability of funds. Particularly, with technically advanced treatment equipment, a cost effectiveness or cost–utility analysis should be prepared that demonstrates that the proposed facility meets the institute's goals in terms of patient work load, clinical capability, and that institutional resources are available to support the programme. The highest priority would, however, be on the assessment of suitability of existing or suggested equipment for the intended purpose — long term financial viability of recurrent costs.

At a national level, the creation of an equitable distribution of access to radiotherapy is a political objective. This will incorporate geographical, cultural and ethnic distinctions within a state in a delicate manner. The radiotherapy development may be a component of a much larger strategy to improve cancer services generally so adding to the complexity of its implementation.

The strategy must have a defined budget and timeline with a clear allocation of responsibility for its implementation across complex functional and administrative boundaries.

7.7. DEVELOPING EFFECTIVE PUBLIC RELATIONS

Good public relations are essential at the outset to avoid misunderstandings; the appointment of a skilled single spokesperson, preferably one of the plan's main authors, is often the best way to handle this. A press office that handles the situation proactively by sending out positive stories of the benefits that will ensue from following the plan will help smooth its entry. For a large reconfiguration, the recruitment of a specialist health media group with good contact with senior journalists will be useful even though the cost may be significant. It is also important to work with clinicians professional societies and educational institutions to obtain their long term support.

8. IMPLEMENTATION AND MONITORING

8.1. ALLOCATING RESPONSIBILITY FOR IMPLEMENTATION

A clear chain of command needs to be established. This includes central management control of the overall plan and its local implementation. Empowered staff who are encouraged to innovate, will be highly motivated to bring their own ideas to the table. Dampening local enthusiasm by stifling the process with bureaucracy is to be avoided.

8.2. PERFORMANCE INDICATORS

Both the development and implementation of a national radiotherapy plan need to be evaluated. Evaluation is a means of monitoring the planning process so that it can be improved. At the plan development stage, evaluation can help answer questions about how well the planning process is working and if the goals and objectives are being met. At the plan implementation level, evaluation can show whether the strategies proposed in the plan are being implemented, and whether the anticipated outcomes are being reached.

Both outcome and process measures need to be monitored. Process evaluation is critical for laying the foundation for success in the future. Gathering feedback from key partners on their satisfaction with the planning process and then making corrections as necessary so that their concerns are addressed are an important part of building trust and credibility. The need to monitor outcome

measures is evident. However, to determine whenever an intervention is likely to achieve its designed purpose, it is also necessary to monitor process measures:

- Resources and staff to conduct the evaluation of both the plan development and its implementation;
- Emerging challenges, solutions and outcomes;
- Identification of those responsible and the time line.

In general terms, an indicator is a variable that helps measure changes directly or indirectly and is used to assess the extent to which objectives and targets are being attained [16]. Indicators provide evidence of the progress towards the attainment of objectives and give the criteria that will be used to monitor and evaluate the success of interventions.

Indicators must be tailored and targeted, relevant, precise, clear, sensitive, specific, objective, reliable, practical and realistic. In addition, the sources of information with which each indicator is to be verified ('means of verification') should be stipulated.

A clinical indicator is defined as a measure of the clinical management and/or outcome of care. Indicators are best seen as measures that screen for a particular event. A well designed indicator should screen, flag or draw attention to a specific clinical issue. Rate based indicators identify the rate of occurrence of an event. Indicators do not provide definitive answers; rather, they are designed to indicate potential problems that might need addressing, usually demonstrated by statistical outliers or variations within data results. They are used to assess, compare and determine the potential to improve care. Indicators can therefore be used as a tool to assist in assessing whether or not a standard in patient care is being met. The indicators provide evidence of performance and can be linked to the appropriate standards.

Clinical indicators can be classified according to the aspects of care they address. Thus, indicators will measure either:

- Structure (what is needed);
- Process (what is done);
- Outcome (what is achieved or expected).

The aims of clinical quality indicators are:

- To facilitate the collection and comparison of national data on the processes and outcomes of patient care.
- To increase the involvement of clinicians in the evaluation of quality improvement activities.

- To create and provide useful tools to screen, flag or draw attention to potential problems and/or areas for improvement in health care.

There is a widespread and growing tendency to develop hospital performance indicators in the field of accreditation systems and quality benchmarking. Quality indicators are designed not only to identify structures of excellence, but mainly to assess operative conditions and draw up plans of action to provide a continuous quality improvement. A comprehensive indicator system should encompass structural, process and outcome dimensions, produce information useful for decision making and become both a sign and source of motivation for quality commitment.

The ability to effect improvements in patient care will largely depend on the relevance of the indicators being monitored. To identify these clinical indicators, which are potentially relevant and appropriate, the following points should be considered:

- Does the indicator measure an important aspect of clinical practice?
- Will the data collected on this indicator assist in improving clinical care?
- Will the information potentially be useful to clinicians in demonstrating how the service is performing and ways that it may be improved?
- Do the indicators relate to and support the strategic intent of an organization?
- Does the organization provide this service?
- Does the organization treat patients within these categories?
- Are there sufficient numbers of patients within these categories for meaningful data to be obtained?
- Will the data be available and accessible to clinicians for its use?

Two sets of indicators are recommended in radiation oncology:

- (1) Indicators of the quality of radiotherapy service at the *radiation oncology centre* level;
- (2) Indicators of the quality of radiotherapy services at the *national* level.

8.3. INDICATORS FOR RADIOTHERAPY CENTRES

At each individual radiation oncology centre, the following statistics should be carefully recorded and reported:

- Total number of cancer patients seen in consult/year;
- Total number of patients treated with radiotherapy/year;
- RUR per disease site (proportion of new cases of cancer treated with radiotherapy);
- Number of patients/radiation oncologist/year;
- Number of high energy units/medical physicist;
- Number of treatment courses/teletherapy machine/year (throughput);
- Number of attendances per radiation therapist.

A set of 13 quality indicators related to the practice of radiotherapy at the level of the radiation oncology centre have been identified [30]. These indicators have been tested in several radiation oncology centres in Italy and are recommended for further use, as presented in the following list (Tables 10–23 [30]).

Each individual indicator is analysed here in terms of its basic dimensions: topic, dimension measured, numerator, denominator, clarifications or specifications, standard and frequency of data collection.

TABLE 10. QUALITY PERFORMANCE INDICATORS FOR RADIO-THERAPY CENTRES [30]

1	G1 — Staff workload
2	G2 — Megavoltage units workload
3	G3 — Waiting times
4	G4 — Clinical record quality
5	G5 — Patient’s opinion survey
6	G6 — Multidisciplinary approach
7	P1 — Megavoltage unit downtime for non-planned maintenance
8	P2 — Instrumentation for dosimetry and quality control (QC)
9	P3 — Equipment QC programmes
10	AC 1 — CT based treatment planning
11	AC 2 — Number of fields per PTV
12	AC 3 — Shaped fields
13	AC 4 — Portal verification

G: General features; P: Medical physics; AC: Accuracy and technical complexity of treatment; Means of verification: data available in each individual radiotherapy centre.

TABLE 11. STAFF WORKLOAD

Topic	Human resource productivity
Dimension	Structure and process
Numerator	Total No. of patients treated in one year
Denominator	Number of workers: (a) radiation oncologists (b) medical physicists (c) RTTs
Specifications	The number of workers should be expressed as full-time equivalents. For radiation oncologists, consider only the time dedicated to patient care (as opposed to research and teaching).
Stratification	By treatment complexity
Standard	(a) 250–300 patients/year/worker (b) 300–400 patients/year/worker (c) 100–150 patients/year/worker Deviations of $\pm 20\%$ are allowed.
Data collection	Continuous, to be analysed once a year.

TABLE 12. MEGAVOLTAGE UNITS WORKLOAD

Topic	Efficiency in megavoltage unit use
Dimension	Structure and process
Numerator	Total No. of patients treated in one year
Denominator	No. of megavoltage units
Specifications	The ratio should not take into account the number of hours a day the units are in use Brachytherapy treatments are excluded
Stratification	By treatment complexity
Standard	200–500 patients/megavoltage unit depending on treatment complexity. This standard is based on a minimum of 7 h/d of equipment activity
Data collection	Continuous, to be analysed once a year.

TABLE 13. WAITING TIMES

Topic	Treatment delay
Dimension	Process
Numerator	Total waiting time (TWT)
Denominator	Number of treated patients
Specifications	TWT measured from the date the patient is ready to start radiotherapy to the start of radiotherapy.
Stratification	According to the treatment's objectives (below)
Standard	(1) Curative/radical ≤ 30 d/patient (2) Palliative ≤ 10 d/patient (3) Pre-operative ≤ 15 d/patient (4) Post-operative/adjuvant ≤ 60 d/patient
Data collection	At least a period of three months every two years

TABLE 14. CLINICAL RECORD QUALITY

Topic	Completeness of clinical data in the clinical record
Dimension	Process
Numerator	Rate scores for various items in the clinical record
Denominator	Number of checked records
Specifications	Each item score should have three levels: (1) Absence or totally inadequate (2) Partial (3) Complete Maximum score = 24 per clinical record
Stratification	According to cancer sites
Standard	Empirical tending to 24 per clinical record
Data collection	At least a period of three months every two years.

TABLE 15. SURVEY OF PATIENTS OPINION

Topic	Patient satisfaction
Dimension	Process
Numerator	No. of questionnaires collected at the end of therapy
Denominator	No. of questionnaires delivered
Standard	At least 66% (2/3) response rate
Data collection	At least a period of three months every two years.

TABLE 16. MULTIDISCIPLINARY APPROACH

Topic	Frequency of multidisciplinary decision-making
Dimension	Process
Numerator	The number of new patients whose initial treatment plan has been discussed at least once in a multidisciplinary setting (tumour board or equivalent).
Denominator	Total No. of new patients in that period
Specifications	The multidisciplinary discussion between at least two different medical specialists has to be reported in the clinical record or special form.
Stratification	According to cancer sites
Standard	≥ 0.70 (>70% of patients)
Data collection	At least a period of three months every two years

TABLE 17. MEGAVOLTAGE UNIT DOWNTIME FOR UNPLANNED MAINTENANCE

Topic	Reliability of maintenance
Dimension	Process
Numerator	No. of days of machine downtime for unplanned maintenance
Denominator	No. of days of machine downtime for planned maintenance
Specifications	A 'day' is defined as a day of downtime of the unit when the number of treated patients is reduced to a third or less of the planned ones
Stratification	For each megavoltage machine
Standard	≤ 1
Data collection	At least one year retrospectively, to be repeated every three years.

TABLE 18. INSTRUMENTATION FOR DOSIMETRY AND QUALITY CONTROL

Topic	Adequacy of instrumentation for dosimetry and QC
Dimension	Structure and process
Numerator	Achieve score
Denominator	Maximum score (e.g. 22)
Specifications	The instruments that should be present in a radiation oncology department are defined. The check should be carried out by an external expert.
Stratification	According to the treatment's objectives (below)
Standard	≥ 0.90
Data collection	To be checked at least once a year without previous notice.

TABLE 19. EQUIPMENT QC PROGRAMMES

Topic	Availability of a protocol for equipment QC
Dimension	Process
Numerator	Achieved score
Denominator	Maximum total score
Standard	≥ 0.85
Data collection	To be checked at least once a year without previous notice.

TABLE 20. CT BASED TREATMENT PLANNING

Topic	Frequency of CT based treatment planning implementation and volume contouring on multiple slices
Dimension	Structure and process
Numerator	No. of CT based treatment plans
Denominator	Total No. of treatment plans processed by the TPS
Stratification	Volume contouring on multiple slices means including the whole clinical target volume (CTV) and organs at risk (OAR) with a maximum interslice distance of ≤ 1.5 cm (excluding the head and neck region)
Standard	≥ 0.75
Data collection	Six months every two years

TABLE 21. NUMBER OF FIELDS PER PLANNED VOLUME

Topic	Complexity of the treatment
Dimension	Process
Numerator	Total No. of planned fields for all PTVs
Denominator	No. of PTVs
Specifications	'Field' is defined as every single port of entry of the radiation beam. A rotation arch is considered equivalent to two fixed fields.
Stratification	For treatment sites as identified by the centre
Standard	Two fields per PTV
Data collection	Six months every two years

TABLE 22. SHAPED FIELDS

Topic	Implementation of shaped fields
Dimension	Process
Numerator	Total no. of shaped fields
Denominator	Total no. of fields
Specifications	A 'field' is hereby defined as every single port of entry of the radiation beam. A 'shaped field' is defined as any focused shielding customized low melting point alloy or other shielding material or through the use of a multileaf collimator.
Stratification	For various treatment sites as identified by the Centre
Standard	≥ 0.85
Data collection	Six months every two years.

TABLE 23. PORTAL VERIFICATION

Topic	Frequency of portal verification
Dimension	Process
Numerator	Total No. of portal verification films in a week
Denominator	Total No. of treated fields in a week
Specifications	Each treatment has to be calculated separately, even when more than one PTV is treated.
Stratification	According to the treatment's objectives (curative, palliative, pre-operative, post-operative)
Standard	≥ 1
Data collection	Three months every two years

8.4. NATIONAL INDICATORS

From a national perspective the following variables are significant to assess the service-providing capacity of a country. Not all the items listed are indicators technically.

8.4.1. Cancer burden

- Population;
- Demographic trends (age specific demographic trends in the next ten years);
- Crude cancer incidence;
- Crude mortality rate for cancer (per 100 000 population);
- Crude incidence rates for the most common cancer types;
- Estimated cancer incidence in the next 15–20 years;
- New irradiated patients/year (excluding skin cancer);
- New irradiated patients/year (including skin cancer);
- Total number of irradiation treatments;
- Re-irradiation factor (proportion of irradiated patients that will require a second course of radiotherapy);
- Total number of megavoltage sessions (fractions);
- Number of treatment courses/treatment machine/year (teletherapy machine throughput);
- Total RUR.

8.4.2. Assessment of national infrastructure

Irrespective of the specific calculations of RURs, the number of teletherapy machines per million of population is an essential indicator for the ability to deliver radiotherapy service.

- Number of radiotherapy centres;
- Number of public access radiotherapy centres;
- Number of private access radiotherapy centres;
- Number of treatment machines;
- Number of operational cobalt units;
- Number of operational linacs;
- Number of orthovoltage machines;
- Teletherapy machines/million population;
- Teletherapy machines/thousand RT patients per year;
- Teletherapy machines/thousand new cases of cancer per year;
- Number of multileaf collimators (MLC);
- Number of remote control afterloading brachytherapy systems;
- Number of HDR remote afterloading systems;
- Number of manual brachytherapy systems;
- Number of fluoroscopic simulators;
- Number of CT simulators;
- Number of computerized TPSs;
- Number of centres implementing advanced radiotherapy techniques;
- Number of centres implementing particle therapy (protons, carbon ions);
- Dedicated in-patient hospital beds for cancer patients.

8.4.3. Staffing

- Number of full time equivalent (FTE) radiation oncologists;
- Number of radiation oncologists/million population;
- Number of radiation oncologists/1000 new cases of cancer per year;
- Number of FTE medical physicists;
- Number of FTE radiation biologists;
- Number of FTE RTTs;
- Number of RTT/teletherapy machine/shift;
- Number of FTE radiation oncology nurses;
- Number of FTE maintenance or biomedical engineers;
- Number of FTE dosimetrists.

8.4.4. Indicators of quality

- Multidisciplinary tumour boards;
- Waiting time for radiotherapy;
- Number of centres requiring informed consent/total number of centres;
- Treatment delay for post-operative radiotherapy for head and neck cancer;
- Chemo-radiotherapy for cervical cancer;
- Follow-up rate for patients treated with radiotherapy for glottic cancer;
- Follow-up rate for patients treated with radiotherapy for breast conservation;
- CT based planning patients/total treated patients;
- Patients receiving brachytherapy/total cervical cancer patients;
- Completion report to referring physician;
- Training programme for radiation oncologists;
- Training programme for medical radiation physicists;
- Training programme for radiation therapy technologists;
- Training programme for radiation oncology nurses;
- Clinical trials participation.

8.5. EVALUATION OF PROJECT TIME LINE

The master plan will have its own time line with the local implementation process contributing a vital part of this. Continuous monitoring of progress with frequent meetings will identify potential problems in advance.

8.6. KEEPING PATIENTS, POLITICIANS AND PROFESSIONALS INFORMED

By developing an effective communication strategy all stakeholders can be kept involved.

8.7. MONITORING OUTCOMES

As the project proceeds to completion, improvement in outcomes should be closely monitored.

8.8. CONTINUOUS IMPROVEMENT OF SERVICES

Improvement in the delivery of radiotherapy is a never ending process. A continuous cycle of planning, implementation and review is essential to drive further improvements in service provision.

9. CONCLUSIONS

A systematic approach should be applied for designing a national radiotherapy programme. An initial evaluation should be completed describing all resources (personnel, equipment and space renovation) required to realize the identified clinical needs such that the resultant programme conforms to acceptable standards of practice. This involves comparing the programme needed to carry out the clinical aims according to accepted practice standards with the available resources, and identifying additional needs.

The options selected will depend on many factors: patient load, clinical training, and the country's priorities and availability of funds. Particularly, with technically advanced treatment equipment, a well defined health technology assessment study should be prepared that demonstrates that the proposed facility meets the country's goals in terms of patient work load, clinical capability, and that national or external resources are available to support the programme.

A strategy to develop or improve radiotherapy services must be multi-pronged and flexible. It must include the following:

- Planning the development of radiotherapy services;
- Investment in equipment and training;
- Linkages with more developed services;
- Access to medical and technical information;
- Education about cancer and the role of radiotherapy;
- QA and radiation safety programmes.

9.1. SUMMARY OF ESSENTIAL STEPS

Establish a normative and regulatory framework for nuclear technologies in accordance to the BSS.

- Determine the national cancer burden.
- Calculate the RUR.
- Assess the current infrastructure:
 - Centres;
 - Equipment;
 - Staff;
 - Procedures.
- Develop/adopt evidence based guidelines for treatment.
- Develop and implement QA programmes.
- Include in them radiation protection standards.
- Assess the current capacity for training (radiation oncologists, medical physicists, RTTs, nurses and maintenance engineers).
- Calculate the need for teletherapy machines.
- Calculate the need for brachytherapy systems.
- Calculate the need for staff to operate such facilities effectively and safely.
- Calculate the gap between existing and required facilities.
- Determine the available resources for the establishment/upgrading of services:
 - National governmental;
 - National non-governmental;
 - External donors;
 - International organizations.

Appendix I

EXAMPLE OF THE DEVELOPMENT OF AN AMBULATORY RADIOTHERAPY SERVICE

I.1. GENERAL

The United Kingdom is developing a pilot project of ambulatory radiotherapy services that will be offered alongside existing centres for care provision. A template is being developed for a network of outpatient cancer centres linked to existing cancer hospitals. They will be open from early morning until late in the evening and will have a medical as well as social function.

These clinics will have the following key characteristics:

- They will be placed in cities throughout the United Kingdom, establishing a local cancer care network for patients;
- They will be a mixture of independent ventures, partnerships with the National Health Service, existing private providers or charities;
- They will be built in existing hospital campuses, or in primary care, business or retail park settings;
- They will have architecturally pleasing environments, be fully equipped to deliver chemotherapy and/or radiotherapy, and to provide a focal point for all non-surgical treatment of cancer;
- There will be different levels of clinics ranging from small outpatient clinics offering only chemotherapy to larger outpatient clinics offering chemotherapy and radiotherapy with two medical accelerators;
- They will operate with full quality assurance control including audit visits.

Because the diagnosis of cancer is so devastating, a unique environment will be created focusing completely on the patient and yet accessing the emerging high technology normally associated with a leading institution. In summary, a patient oriented radiotherapy service will be created.

The patient's environment will:

- Be welcoming, calm and unhurried;
- Avoid delays;
- Be comfortable and provide contemporary furniture and a feeling of spaciousness;
- Provide a suitable waiting room décor;
- Offer refreshments;

- Provide clean, tidy and welcoming treatment rooms;
- Provide a thorough explanation of the steps within the radiotherapy pathway;
- Provide changing cubicles, screens and patient escort;
- Ensure patient privacy and dignity;
- Provide appropriate interpreting facilities;
- Provide continual reassurance and appropriate follow-up information;
- Provide rapid referral to chemotherapy services if required.

The availability and sustainability of human resources and infrastructure to support a highly specialized service is of utmost importance.

Highly specialized radiation oncology services should only be considered in an environment capable of thorough self-evaluation. Any introduction of new technology should be accompanied by a concurrent exercise in ensuring radiation safety, updating quality management and provide assurance that clinical outcomes are at least maintained. The following should be mandatory to all personnel involved in specialized radiotherapy services: continued professional education and development including direct international exposure and participation and interaction, at the individual level with others, to share the clinical and scientific impact of new technologies as they develop and progress. This implies that there is a standard service with evidence of outcomes, survival and documented incidence of morbidity and mortality.

I.2. EUROPEAN SERVICE PLANNING GUIDELINES

Given the need to network specialized devices, staff computer literacy, database security and system management are essential. In addition, the logistics required to enable availability of the radiotherapy team in order to initiate treatment becomes more critical in image guided techniques. The need for integrated dosimetry equipment to ensure adequate quality control, pre-treatment quality assurance and the management of imaging dose places an additional burden on the medical physics staff. The availability of specialist consultations with other disciplines, e.g. neurosurgery for stereotactic radiotherapy, radiology for high end functional imaging, etc., is then also more critical to radiation oncology patient management. In order to collect the existing guidelines for infrastructure and staffing for radiotherapy in Europe, and consequently to develop general guidelines, a project supported by the European Union was started in ESTRO (QUARTS) in 2003.

Since it was suspected that not only the actual provisions, but also the real indications for radiotherapy vary considerably in different parts of the European Union, the QUARTS group has tried to clarify the need for radiotherapy

infrastructure and staffing. It was investigated whether national guidelines exist and whether it is possible to calculate a more detailed estimation of the need according to data on specific cancer incidences in various countries. A database of the existing radiotherapy centres and staffing was also established.

A questionnaire [31] was sent to a large number of European countries and a response was obtained from 41 countries, representing 99.4% of the total population of 809 million in the European Union.

In a second step, the data on availability of radiotherapy infrastructure were correlated with the specific cancer incidence of the most important tumour locations, for which the indications for radiotherapy were separately calculated [20]. The result of this exercise was illuminating: the crude incidence of the most important cancer types varies considerably in European countries, reflecting differences in cancer causes and more importantly, differences in age structure.

From the data it became clear that there is a wide range in the number of high energy apparatuses in these countries (e.g. France has 6.1, the United Kingdom (England) has 3.1) and even within countries (e.g. the United Kingdom 2.1–6.02). This variation in availability is obviously reflected in an important variation in the use of radiotherapy correlated to the cancer incidence (again, in the United Kingdom (England) 22– 58% of all cases).

In some regions, the lack of adequate infrastructure is reflected in waiting lists that have become unacceptably long. In addition, these waiting lists are likely to have a detrimental effect on general treatment outcome in cancer treatment.

Most assumptions for radiotherapy needs are based on the crude assumption that 50% of cancer cases need radiotherapy in the course of the disease. In the QUARTS programme, an effort was made to base this forecast of needs on clinical evidence of appropriate RURs. Indeed, to estimate the required number of megavoltage treatment units, four important factors must be taken into account:

- The proportion of patients with a given cancer type presenting a radiotherapy indication the specific incidence of these cancer types;
- The re-treatment rate;
- The number of treatments per year per megavoltage unit.

The QUARTS report [20] based the calculation of these RURs on several publications on evidence based indications for radiotherapy, from Sweden, Canada and Australia [7, 30, 31]. The number of treatments possible per megavoltage unit in normal treatment hours was considered 450 per year (Table 24). For the purposes of this study, the performance of cobalt units and linacs, in terms of treatments per year were considered equivalent.

TABLE 24. ESTIMATED NEED FOR TELETHERAPY MACHINES PER NUMBER OF PATIENTS AND PER POPULATION^a

Guideline	Per patient	Per population
Linear accelerators		
— General	1 per 450 patients/year	1 per 180 000 persons
— With increasing complexity	1 per 400–450 patients/year	1 per 160–180 000 persons
Radiation oncologists		
— General	1 per 250 patients/year	1 per 100 000 persons
— With increasing complexity	1 per 200–250 patients/year	1 per 80–100 000 persons
Physicists		
— General	1 per 450–500 patients/year	1 per 180–200 000 persons

^a The numbers per population are based on the assumptions of a radiotherapy utilization factor of 50% and a retreatment factor of 1.25.

More accurate population based needs for radiotherapy infrastructure and staffing can be obtained using the approach described in Ref. [20].

A weighting factor was used taking into account the complexity of the treatment per cancer site: the average number of fractions for these sites over the total of radiotherapy courses resulted in certain factors, e.g. for the head and neck, 1.58; for colorectal, 0.38 (due to the much used 5 Gy × 5 Gy for preoperative irradiation); for non-Hodgkin's lymphoma, 0.7. Data on the number of incident cases were obtained from the Eucan and Globocan databases where the crude incidence was used to evaluate the appropriate number of radiotherapy facilities. This crude incidence can differ markedly from the age adjusted incidence rates due to the different age structure in different countries.

Taking into account all these data, an estimate was possible of the needs for treatment units in each country: the incidence data for each of the 23 cancer sites in the Eucan Globocan databases were multiplied by the RUR for these sites (as derived from the CCORE studies [7]). A uniform retreatment factor of 1.25 was applied, and a weighting factor concerning the required number of fractions was also required. The incidence of these 23 sites was compared to the incidence of all cancer sites provided by the databases, and it was found that these sites accounted for about 90% of the total cancer incidence in the 25 European countries. An assumption was made that about half of the remaining 10% would need radiotherapy indication. The result was very instructive: the need for radiotherapy as expressed by the number of linacs required per million people varies all over Europe by a factor of 2 (4 in Cyprus, 8.1 in Hungary) with an average of 5.6 per million (Fig. 5).

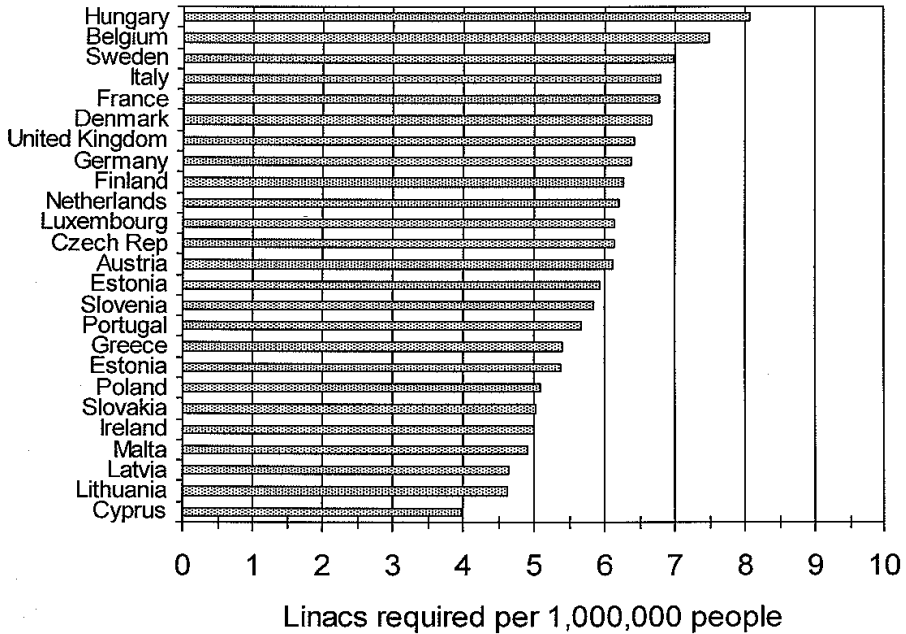


FIG. 5. QUARTS estimates of the number of linacs (or megavoltage RT units) required per one million people in each of the 25 countries in the European Union in 2003. Source: Ref. [20].

Another instructive exercise was performed concerning these calculated needs: it was possible to compare them to the actual practice in different countries since data were available in the QUARTS database. In this way, it was possible to calculate the gap between the current provision and the estimated need. In some countries, the actual provision was not far off the guidelines, although these did not necessarily reflect the real needs. If the actual provision is expressed as a percentage of the estimated need as calculated, it is clear that there is a spectrum within some country (nearly sufficient) capacity, while in other countries this capacity is clearly too low.

Appendix II

TECHNIQUES FOR PRECISION RADIOTHERAPY

II.1. INTENSITY MODULATED RADIOTHERAPY

Intensity modulated radiotherapy (IMRT) uses cutting edge computer technology to produce complex, sculpted dose distributions that increase the dose to the tumour and decrease the dose to surrounding healthy organs. To deliver accurate radiotherapy, it is imperative to ensure that the patient's position, and thus the location of the tumour and surrounding tissues, is the same each time. A computer controlled multileaf collimator in the output head of the linac (Fig. 6) allows the shape of each beam to be tailored to deliver the optimal high dose volume. The dynamic tungsten leaves in the collimator can change the shape of the beam even during the course of its delivery so increasing the number of possible shapes of the treatment volumes produced. Concave and convex plans can be produced to avoid critical normal structures in a way not possible by conventional planning processes. The planning phase of IMRT requires sophisticated software and skilled dosimetric and medical physics support. More time is required to ensure the planned tumour volume proposed by the clinician is accurately configured. This increases the cost of both planning and delivery. An algorithm for the indications for IMRT and image guided radiotherapy (IGRT) is shown in Fig. 7.



FIG. 6. A multileaf collimator in the linac treatment head.

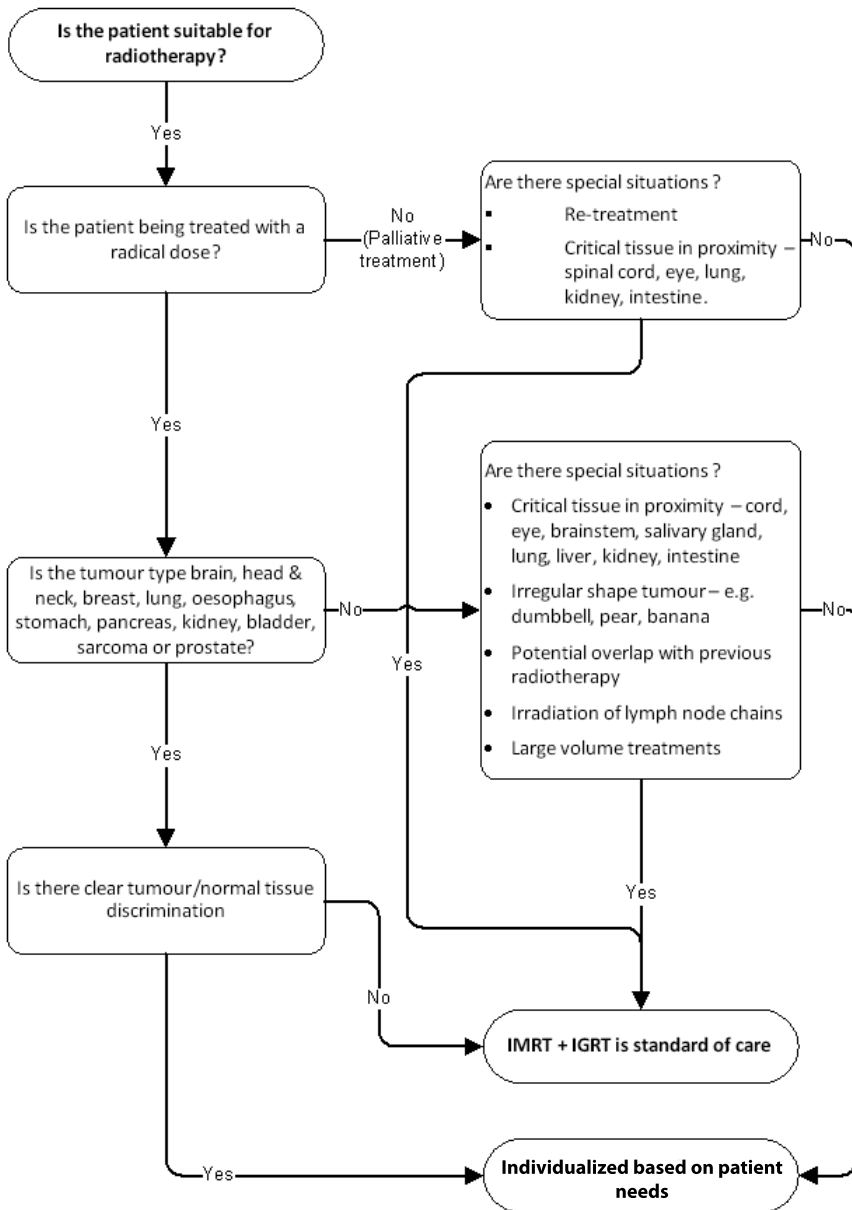


FIG. 7. Decision making process for advanced radiotherapy techniques.

II.2. IMAGE GUIDED RADIOTHERAPY

Traditionally, ink marks on the patient's skin have been used to position them on the linac couch for every treatment. The megavoltage treatment beam has then been used to produce planar images, on film or digital detectors, to image the bony anatomy and thus verify the position of the treatment fields. This method assumes the position and shape of the tumour and critical surrounding normal tissues are fixed with respect to the bony anatomy, which is often not the case, and relies on planar megavoltage images, which are not very clear. Both of these problems have been solved by the advent of IGRT, in which kilovoltage imaging equipment, as used in diagnostic radiology, has been attached to the linac to produce planar images at the time of treatment which are superior to the traditional megavoltage images. This latest technology can also be used to generate cone beam CT (CBCT) images to visualize the tumour and surrounding healthy tissue — and daily changes in shape and position of both — immediately prior to each treatment. The use of IGRT, including CBCT, enables patients to be re-positioned to improve their setup accuracy, and the accuracy of their treatment, immediately before the radiation dose is delivered.

II.3. ADAPTIVE RADIOTHERAPY

It is well known that the contours of the patient and the size of the tumour may change over several weeks of treatment. The use of IGRT equipment to acquire CBCT images allows these changes to be visualized and the patient's treatment plan to be adapted appropriately over the course of treatment. As TPSs improve in speed and functionality, it should be possible to use CBCT images taken just before treatment to adapt the treatment plan for that treatment — Dynamic Adaptive Radiotherapy.

II.4. RESPIRATORY GATING/4-DRT

This allows the latest planning, treatment and imaging equipment to adapt a patient's treatment to changes that are inevitably introduced over their breathing cycle. Essentially, the linac adapts to the patients breathing pattern, switching the beam off when the tumour moves outside the planned treatment volume and switching it back on when it comes back into position. This technique further enhances the accuracy of dose delivery in an individual patient and permits critically radiosensitive structures to be avoided during chest and abdominal radiotherapy. Respiratory gated or 4-D radiotherapy (time being the fourth

dimension) is currently used in special circumstances where absolute accuracy is required in parts of the body where breathing movements critically changes the internal anatomy.

II.5. IMRT AND IGRT IN CLINICAL PRACTICE

Quality radiotherapy and IMRT cannot be delivered without comprehensive IGRT. Figure 8 shows an example of the benefits of IMRT/IGRT in prostate cancer treatment. Here the critical neighbouring structure is the rectum, which actually lies just behind the prostate. If this is included in the treated volume, serious early and late side effects are inevitable. Table 25 lists the critical structures in different parts of the body. Figure 9 shows the use of IMRT in breast cancer where the delivery of a homogeneous dose is challenging because of the highly individual and irregular shape gradients of the female breast. Here IMRT is used to compensate in a tailored manner for the inevitable irregularities.

IMRT/IGRT is now standard practice internationally for most treatments where cure is the aim. Randomized trials of conformal therapy performed in the 1990s led to the widespread adoption of this technique and randomized trials of IMRT carried out in recent years are continuing to amass evidence with very positive the results to date. Such trials are unlikely for IGRT, however, as it is not a change in treatment technique, but rather a vast improvement in patient imaging and pre-treatment setup. The advantages of imaging the patient and correcting their setup before treatment seem obvious and it is unlikely that centres will be willing to randomize a control group to be ‘treated blind’ if IGRT equipment is available to them.

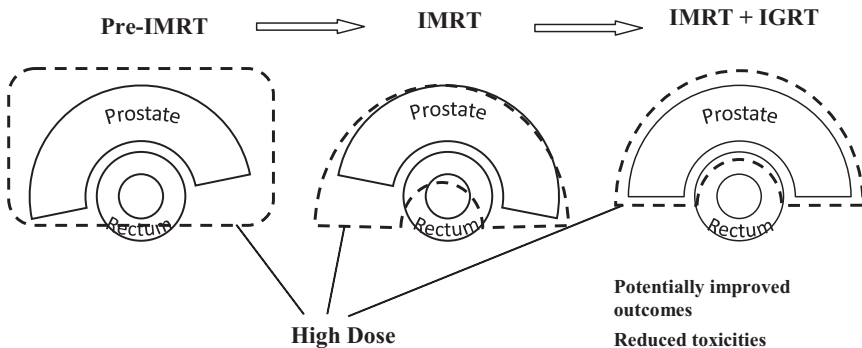


FIG. 8. Prostate cancer radiotherapy — the benefits of IMRT/IGRT.

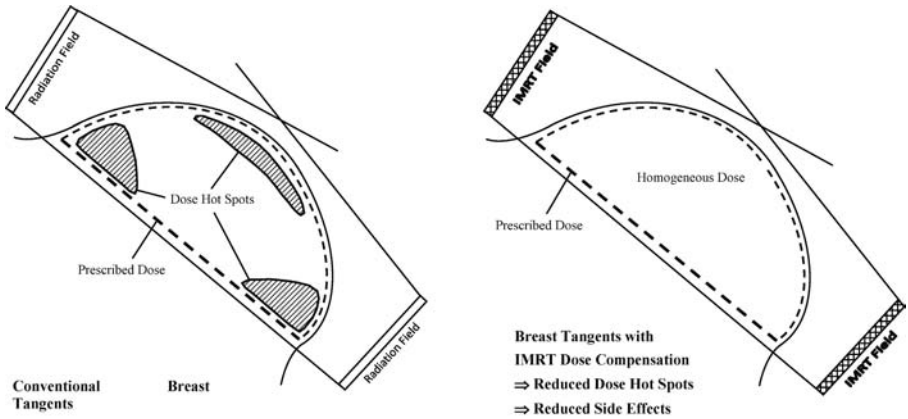


FIG. 9. Breast cancer radiotherapy using IMRT as a compensator to achieve dose homogeneity.

TABLE 25. CRITICAL RADIOSENSITIVE ORGANS IN DIFFERENT REGIONS OF THE BODY

Site	Critical organ
Head and neck	Eye, brain stem, spinal cord, salivary glands
Chest	Spinal cord, lung
Abdomen	Liver, kidneys, small intestine
Pelvis	Bladder, rectum, sigmoid, small intestine

The patient is likely to live for many years after treatment and thus reducing the potential for long term collateral damage is essential. Not all patients may need IMRT as the anatomy of the tumour and normal tissue may permit clear discrimination without it. With palliative treatment, however, long term survival is unlikely and the delivered dose relatively low. IMRT may be indicated in special situations such as where tumour is impinging on a vital structure or the patient has been previously treated with radiation. In contrast, all patients will benefit from IGRT and it would be hard to justify not using it if the equipment is available.

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ABBREVIATIONS

ARR	appropriate rates of radiotherapy utilization
CTV	clinical target volume
FTE	full time equivalent
GNI	gross national income
GTV	gross tumour volume
imPACT	Integrated Missions of the IAEA Programme of Action for Cancer Therapy (PACT)
NCRP	National Council on Radiation Protection and Measurements (USA)
OAR	organ at risk
PTV	planning target volume
QALY	quality adjusted life year
QOL	quality of life
SQL	Structured Query Language
TWT	total waiting time

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